



Australian Government
Department of Health
Therapeutic Goods Administration

Usability evaluation of Consumer Medicine Information (CMI) documents

Insights and recommendations report

Prepared for the TGA by
ThinkPlace Australia and The University of Sydney
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TGA Health Safety
Regulation



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Executive Summary

Project intent

Evaluate the usability of revised Consumer Medicine Information (CMI) formats with consumers and produce an improved CMI template that supports better understanding of medicines information.

Project background and intent

The TGA engaged ThinkPlace, together with project partners Prof. Parisa Aslani – Professor of Medicines Use Optimisation at The University of Sydney, to evaluate the usability of three revised CMI formats developed by the CMI Electronic Distribution Working Group (EDWG), and produce a new and improved CMI template.

In 2008-2010, The University of Sydney conducted extensive research, the *Investigating Consumer Medicine Information (I-CMI) Study*, funded by the Australian Department of Health, on the usability and effectiveness of CMI documents.

The I-CMI study had developed, consumer user-tested, and evaluated several alternative CMI formats in community pharmacies with pharmacists and consumers.

The CMI Electronic Distribution Working Group (EDWG) conducted additional reviews of the alternative CMI formats in 2015, which identified the need for a short, one-page summary, to accompany the full CMI.

In late 2018, the Minister for Health requested a review and development of a CMI template.

In response, the EDWG worked with the TGA to develop example revised CMI formats based on the CMI templates from the previous work.

Three medicines were chosen to represent various dosage forms – oral, injectable and inhaler: Plavix®, Ultibro® and Toujeo®, respectively.

These revised CMI formats were to be tested with consumers, to evaluate and identify further improvements.

ThinkPlace was engaged to conduct the evaluations, and partnered with Prof. Parisa Aslani to ensure consistency of approach and expertise from their previous research for the I-CMI study.

The project aimed to:

- evaluate and improve the revised CMI formats through iterative cycles of usability evaluation and design.
- explore opportunities provided by digital formats and delivery to help improve use of CMI content.
- better understand user behaviours and preferences for using CMI.
- identify considerations for a longer-term vision and continuous improvement of CMI.
- engage and secure endorsement from stakeholders for the updated CMI.

This project leveraged the previous research conducted by The University of Sydney to inform the design improvements and measure comparable results during the usability evaluations.

Project approach at a glance

The research and design team took the three revised CMI formats (for Plavix[®], Ultibro[®] and Toujeo[®]) developed by the EDWG, and followed a user-centred approach over three weeks of rapid usability evaluations with consumers and design iterations in two streams: print and digital.

Usability evaluations used a mixed method of interviews combined with observed task completion to gather both qualitative and quantitative findings.

The University of Sydney team used User Testing, the Australian-developed method, which is used in Europe to determine the usability of patient leaflets.

For each week, we synthesised these findings between the two streams – print and digital – to identify features that worked well, and those that could be improved in the following iteration.

The primary focus was on evaluating how well the CMI documents communicate medicine information to the users.

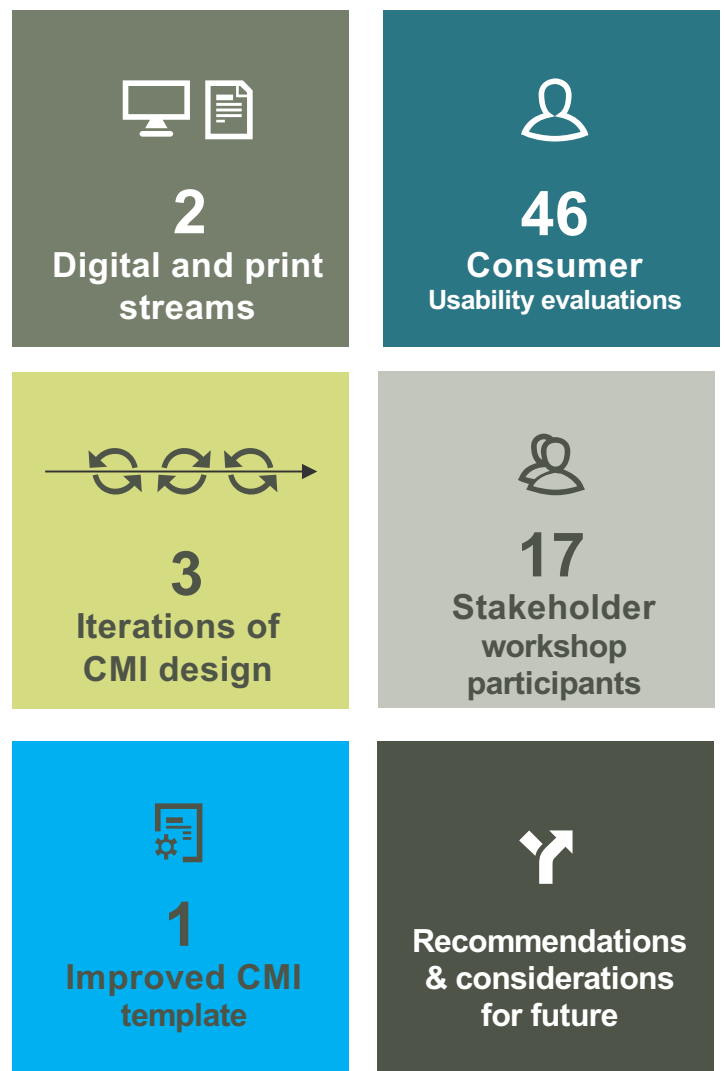
The secondary focus was on the design elements of the documents being tested, such as layout, headings, plain English, and for the digital stream – on navigation features.

We did not focus on the clinical content of the CMI.

We had four broad areas or themes by which the CMI's were evaluated:

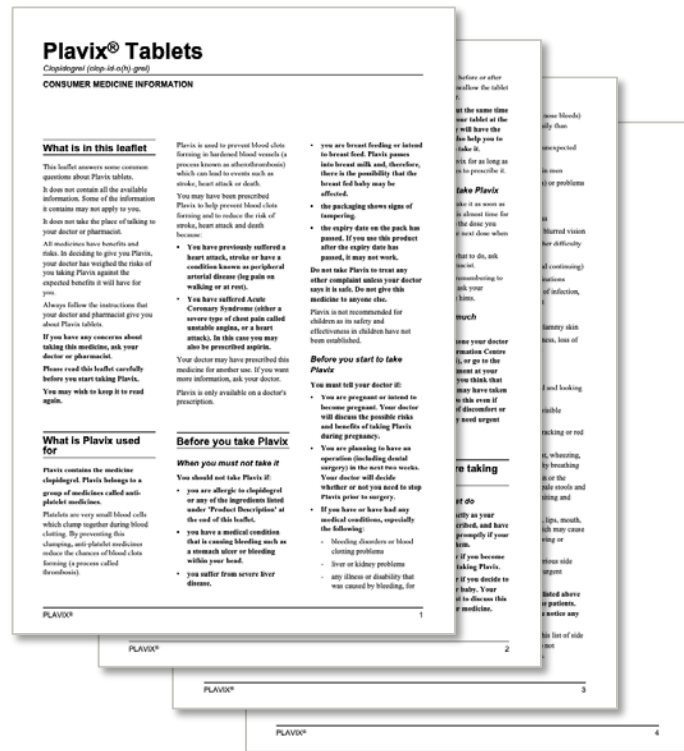
- Findability of information.
- Comprehension of information.
- Actionability of the information.
- Context of use.

Final insights and CMI designs were shared in a workshop with stakeholder representatives from across industry, consumer and pharmacy organisations to gather input for implementation and other considerations for the future.

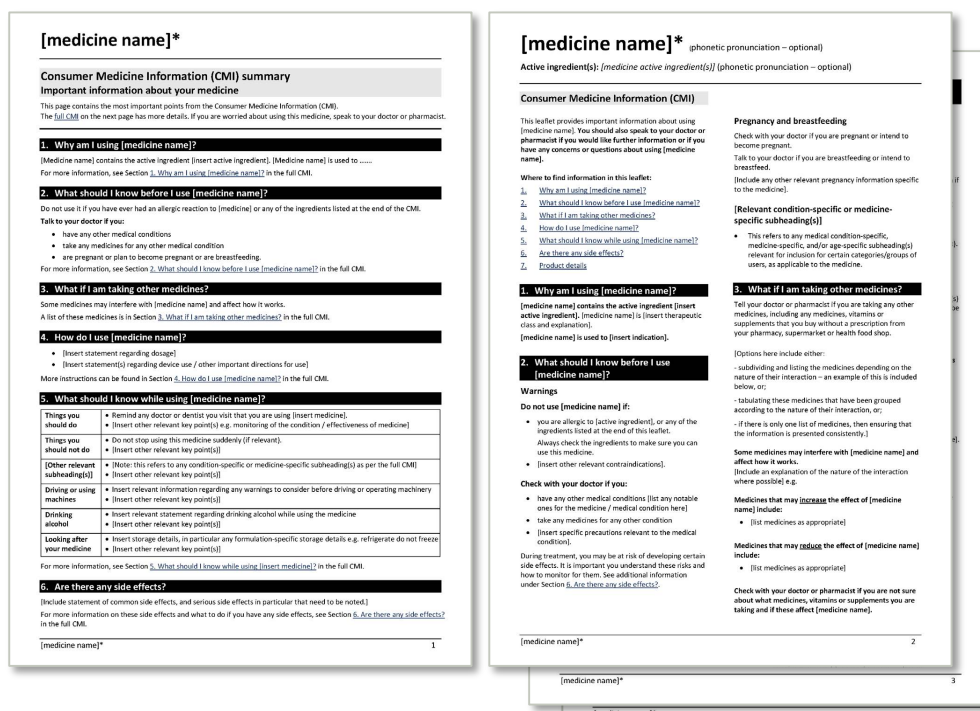


The changes at a glance

The current CMI format



The improved CMI template, with summary page



Summary of key improvements

Following the three rounds of testing, and the industry workshop, the print version of the CMI template has incorporated a number of features which improve usability.

The CMI template was evolved by The University of Sydney from the original versions provided by the EDWG, drawing on their expertise and experience with medicine information, and responding to insights from both streams of usability evaluations, and decisions made in conjunction with ThinkPlace designers, TGA project team and supported by participants at the workshop.

Improved findability of information through:

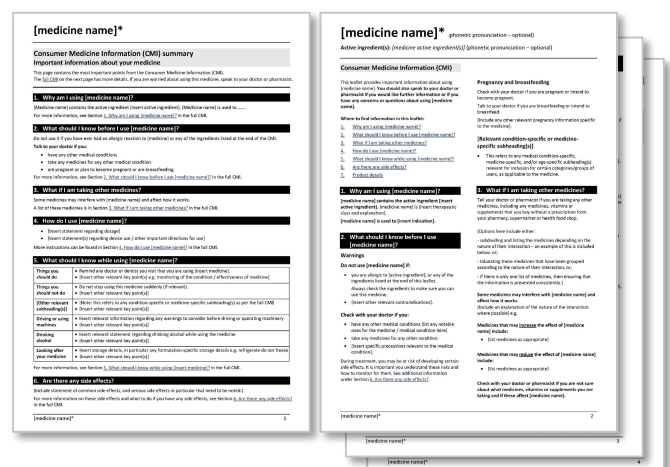
- Introduction of a concise summary page, linked to the full CMI.
- Numbered headings and clearer heading hierarchy, consistent across both summary and full CMI.
- Content index and meaningful cross-referencing.
- Good information writing and design principles governing layout and style of content.

Improved actionability through:

- Tabular layout and content grouping, and clarity of actions to take for critical information, such as side-effects and ingredients.
- Clear presentations of actions to take for precautions and contraindications.
- Tabular layout of actions for section 5 of the summary CMI: “What should I know while using [medicine name]?”

Improved comprehension through:

- Improved readability with the reduction of columns for the full CMI (two for print, and one for digital) and reduced amount and density of text.
- Use of plain English throughout.
- Use of consistent wording when conveying similar information.



The improved CMI template in detail

A final revised CMI template was produced by The University of Sydney research team based on, and underpinned by the:

- user testing findings from this study, primarily The University of Sydney quantitative findings,
- evidence-based findings from the current CMI research in the literature,
- existing national and international guidelines to support written medicine information development, and
- feedback received on the three study CMIs and the draft template presented at the stakeholder workshop.

Unique features of the CMI template

summary CMI with key points mapped to the full CMI (page 1 of the template)

- Tabulating key points under the heading “5. What should I know while using [medicine name]?”
- Links / cross-referencing to individual sections in the full CMI to improve document navigation from the summary CMI.
- Consistent formatting between the summary and full CMI.
- Presenting key points under the same headings / subheadings within the summary and full CMI for consistency.

Revised grouping and tabulation of side effects (page 4 of the template)

- Inserting separate tables for side effects based on the side effect severity and the recommended action(s) to be taken.
- Subgrouping of side effects within each table according to their effect on the body.
- Clear subheadings to highlight the side effect severity and any further subgrouping within each table.

[medicine name]*

Consumer Medicine Information (CMI) summary
Important information about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI). The full CMI is on the next page. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using [medicine name]?
(Medicine name) contains the active ingredient(s) [insert active ingredient(s)]. (Medicine name) is used to...
For more information, see Section 5, [What should I know before I use \[medicine name\]?](#) in the full CMI.

2. What should I know before I use [medicine name]?
Do not use it if you have ever had an allergic reaction to (medicine) or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you:

- have any other medical conditions
- take any medicine for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 5, [What should I know before I use \[medicine name\]?](#) in the full CMI.

3. What if I am taking other medicines?
Some medicines may interfere with (medicine name) and affect how it works.
A list of these medicines is in Section 5, [What should I know before I use \[medicine name\]?](#) in the full CMI.

4. How do I use [medicine name]?

- (Insert statements regarding dosage)
- (Insert statements) regarding device use / other important directions for use

More instructions can be found in Section 5, [What should I know before I use \[medicine name\]?](#) in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	<ul style="list-style-type: none"> • Read the full CMI or device use instructions that you are using (insert medicine) • (Insert other relevant key point(s) (e.g. monitoring of the condition / effectiveness of medicine))
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly (if relevant) • (Insert other relevant key point(s))
Other relevant subheadings	<ul style="list-style-type: none"> • (Insert this refers to any condition specific or medicine specific subheadings as per the full CMI)
Driving or using machines	<ul style="list-style-type: none"> • Insert relevant information regarding any warnings to consider before driving or operating machinery • (Insert other relevant key point(s))
Drinking alcohol	<ul style="list-style-type: none"> • Insert relevant statement regarding drinking alcohol while using the medicine • (Insert other relevant key point(s))
Looking after yourself	<ul style="list-style-type: none"> • Insert encourage advice, to particular any formulation specific storage details (e.g. refrigerate do not freeze) • (Insert other relevant key point(s))

For more information, see Section 5, [What should I know while using \[insert medicine name\]?](#) in the full CMI.

6. Are there any side effects?
(Insert statement of common side effects, and serious side effects if applicable. (Not need to be worried).
For more information on these side effects and what to do if you have any side effects, see Section 5, [Are there any side effects?](#) in the full CMI.

[medicine name]*

6. Are there any side effects?
All medicines can have side effects. If you do experience any side effects, report them to your doctor and pharmacist. Some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
(Inserting a side effect on body (e.g. itching, rashes)) • (list as appropriate) (Inserting a side effect on body) • (list as appropriate)	Speak to your doctor if you have any of these less serious side effects and they worry you. (Insert appropriate action)

Serious side effects

Serious side effects	What to do
(Inserting a side effect on body (e.g. breathing problems)) • (list as appropriate) (Inserting a side effect on body) • (list as appropriate)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.
Other side effects not listed here may occur in some people.

Reporting side effects
After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [https://www.tga.gov.au/reporting-problems](#). By reporting side effects, you can help provide more information on the safety of this medicine.
Already make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

[medicine name]*

7. Product details
This medicine is only available with a doctor's prescription.

What [medicine name] contains

Active ingredient (main ingredients)	(insert)
Other ingredients (inactive ingredients)	(insert)

Do not take this medicine if you are allergic to any of these ingredients.

What [medicine name] looks like
(medicine name) is: (Insert description)

Who distributes (medicine name)
(insert) (insert name and contact details)

This leaflet was prepared in (insert month and year).

The improved CMI template in detail

Unique features of the CMI template (continued)

Tabulation of the medicine ingredients (page 4 of the template)

- Tabulating active and inactive ingredients.
- Medicine ingredients moved higher up in the section “7. Product details”, before information about what the medicine looks like.

A subheading called “Warnings” under the heading “2. What should I know before I use [medicine name]?” (page 2 of the template)

Evidence-based elements that continue to support optimal document design and usability:

Good information design

- Bolding of key actions to be taken and key messages, for emphasis.
- Increasing white space between lines to help make the information easier to read.
- High contrast headings throughout the document (white font on dark coloured background / band).
- Numbering headings to support document navigation.
- Using appropriate subheadings within the key headings to help group and emphasise information.

Appropriate content and wording

- Using plain English throughout the document.
- Defining all medical / scientific terms.
- Using clear statements.
- Using consistent wording when conveying similar information.
- Reducing unnecessary repetition throughout the document.

[medicine name]* (phonetic pronunciation – optional)
Active ingredient(s) [medicine active ingredient(s)] (phonetic pronunciation – optional)

Consumer Medicine Information (CMI)

This booklet provides important information about using [medicine name]. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].

When to find information in this booklet:

1. **Why am I using [medicine name]?**
2. **What should I know before I use [medicine name]?**
3. **What if I am taking other medicines?**
4. **How do I use [medicine name]?**
5. **What if I forget to use [medicine name]?**
6. **What if I am pregnant or breastfeeding?**
7. **What if I am taking other medicines?**
8. **What if I have any side effects?**
9. **What if I have any other concerns?**

Why am I using [medicine name]?
[medicine name] contains the active ingredient [insert active ingredient]. [medicine name] is used to [insert specific use and explanation].
[medicine name] is used to [insert indication].

What should I know before I use [medicine name]?
Warnings
Do not use [medicine name] if:

- you are allergic to [active ingredient], or any of the ingredients listed at the end of this booklet.
- Always check the ingredients to make sure you can use this medicine.
- Insert other relevant contraindications.

Check with your doctor if you:

- have any other medical conditions (for any reason open for the medicine / medical condition here).
- take any medicines for any other condition.
- insert specific precautions relevant to the medical condition.

During treatment, you may be at risk of developing serious side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 8, [insert section number and title].

What if I am pregnant or breastfeeding?
Check with your doctor if you are pregnant or intend to become pregnant.
Talk to your doctor if you are breastfeeding or intend to breastfeed.
Include any other relevant pregnancy information specific to the medicine.

What if I am taking other medicines?
[Relevant condition-specific or medicine-specific subheadings]

- This may cause a medical condition-specific, medicine specific, and/or age-specific side effect(s) relevant for patients for certain categories of users, as applicable to the medicine.

[Insert here include either:

- subheading and listing the medicines depending on the nature of their interaction – an example of this is included below; or
- tabulating these medicines that have been grouped according to the nature of their interaction; or
- if there is a very rare fatal medicine, then ensuring that the information is presented concisely.]

Some medicines may interact with [medicine name] and affect how it works.

- [Insert medicines as appropriate]

Medicines that may [insert the effect of [medicine name] and] include:

- [Insert medicines as appropriate]

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].

[medicine name]* 2

6. How do I use [medicine name]?
How much to take / use

- Include relevant dosage information.
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

When to take / use [medicine name]

- [medicine name] should be used [insert as relevant].
- Insert relevant step by step instructions / considerations for device use.

How to [insert appropriate verb] [medicine name] [insert for device]

- Insert relevant step by step instructions / considerations for device use.

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also help to distinguish external links from internal document sections.

If you forget to use [medicine name]
[medicine name] should be used regularly at the same time each day (week or month). If you miss your dose at the next time, insert appropriate explanation.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

Do not stop using [medicine name] suddenly (if relevant).

Things you should not do

- Do not stop using [medicine name] suddenly (if relevant).
- Include any other relevant actions.

Relevant condition-specific or medicine-specific subheadings

- Some medicines may cause additional side effect(s) relevant to [insert the condition and/or medicine].
- Be aware of symptoms, the condition and/or action to be taken while on the medicine e.g. bleeding risk with [insert condition / symptoms and/or action to be taken].

Driving or using machines
Be careful before you drive or use any machines or tools until you know how [medicine name] may affect you. [medicine name] may cause dizziness in some people (or insert relevant information, as appropriate).

Drinking alcohol
Tell your doctor if you drink alcohol.
Alcohol may [insert effect relevant to use of the medicine].

Looking after your medicine

- Include dose-specific storage information.
- Include storage information (e.g. follow the instructions in the container on how to take care of your medicine properly).
- Store in a cool dry place away from moisture, heat or sunlight for example, do not store in:
 - in the bathroom or near a sink, or
 - in the car or on window sills.
- Do not use this medicine after the expiry date.
- Keep it away from young children cannot reach it.

When to discard your medicine (as relevant)
Include any specific information in discarding the medicine e.g. [insert expiry from date of first use].

Getting rid of any unwanted medicine
If you no longer need to use this medicine or it is out of date, take it to a pharmacy for safe disposal.

[medicine name]* 3

The digital CMI prototype

The ThinkPlace digital stream developed and tested responsive HTML prototypes based on the CMI template developed by The University of Sydney.

The focus was to evaluate usability of the CMI when accessed and viewed online via desktop computers and mobile devices, and to inform future directions for digital distribution of CMI.

Unique features of the digital CMI prototype

- Improved orientation to document structure by inclusion of index menu up front.
- Summary and detailed information available through expandable panels to aid findability of content, and reduce disorientation caused by scrolling through large amounts of text.
- Mobile responsive layout to improve readability on smaller screens and prevent missing content (when users zoom documents to a readable size in one column, the second is hidden off-screen).
- Fixed header information to aid navigation and wayfinding.
- Single-column layout to aid readability and prevent missed information on smaller screens.
- Product image up front to aid recognition and comprehension of dosage form.
- Use of colour (red) in critical warnings such as serious side effects.



Approach and methods

The qualitative and quantitative approaches taken by the two research streams to gather the feedback from consumers.

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Iterative evaluation and design

The approach taken to evaluate and improve the CMI template involved two parallel research streams conducting usability evaluations of evolving design changes to print and digital revised CMI formats.

Print stream

The print stream, conducted by The University of Sydney, designed the print versions of the revised CMI formats and based their methods for usability evaluations on the process developed by Sless et al¹. This method is widely implemented in the European Union within the pharmaceutical industry to evaluate the performance of medicine information leaflets and ensure that their performance meets required benchmark standards.

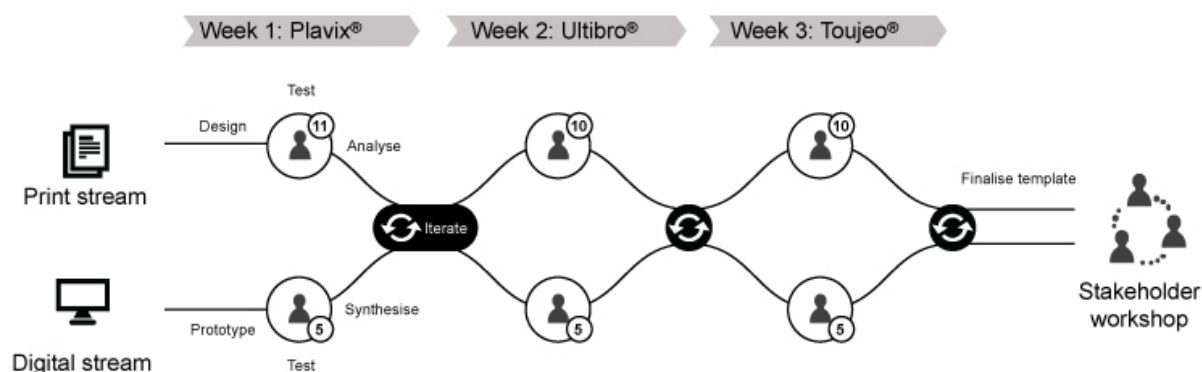
The user testing process consisted of evaluating the usability of the CMI via the administration of a validated user testing questionnaire, and evaluating a consumer's ability to find medicine information, and interpret the information found.

More detail on The University of Sydney's specific methods can be seen in *Appendix D and F*.

Digital stream

The digital stream, conducted by ThinkPlace Australia, adapted the print CMI formats to digital formats, and followed a mixed method of structured interviews, with task-based usability evaluation, gathering qualitative findings based on observed behaviours and interview responses around findability, comprehension and actionability. Questions were included from the print stream method to enable comparative synthesis between the two streams.

After each week, the two teams would compare findings gathered through analysis and synthesis and agree on changes to be made in the following week's design and prototype iterations.



¹Sless D, Shrensky R. *Writing about medicines for people: usability guidelines for Consumer Medicine Information*. 3rd ed. Sydney: Australian Self Medication Industry; 2006

Who we spoke with

The two research teams conducted usability evaluations with a total of 46 participants: 31 for the print stream and 15 for the digital stream.

All participants had to meet the following criteria¹⁻⁴:

- ≥ 18 years.
- English skills sufficient to take part in the study.
- Not on the study medicine or a medicine in the same class.
- Not a health care professional.
- Not visually or cognitively impaired.
- Not participated in user testing in the past 6 months.

For each CMI tested, participant cohorts were demographically matched according to the following criteria¹⁻⁴:

- **Age:** at least one in each decade between 30 and 70+ years.
- **Sex:** minimum of three per sex (at least two for the digital stream).
- **Education:** no more than three higher education graduates (no more than two for the digital stream).
- **Written information use:** at least two who either do not regularly use written documents as part of their work, or who are currently not working or retired.

¹Aslani P, Hamrosi K, Feletto E, Raynor DK, Knapp P, Parkinson B, et al. Investigating Consumer Medicine Information (I-CMI) Project. Sydney: The Pharmacy Guild of Australia, Australian Government Department of Health and Ageing, 2010.

²Tong V, Raynor DK, Aslani P. Developing alternative over-the-counter medicine label formats: How do they compare when evaluated by consumers? Research in Social and Administrative Pharmacy. 2018;14(3):248-61.

³Tong V, Raynor DK, Aslani P. Comparative user testing of Australian and UK over-the-counter labels and leaflets for diclofenac. Therapeutic Innovation & Regulatory Science. 2018;52(1):38-48.

⁴Aslani P, Tong V. Developing standards for labelling dispensed medicines: report on user testing findings. Sydney, Australia: The University of Sydney, 2019.

Stakeholder workshop

At the conclusion of the usability evaluation, ThinkPlace and The University of Sydney teams facilitated a half-day workshop with 17 representatives of consumer groups, industry bodies, government and health care professionals.

The workshop showcased the results from the usability evaluations, and the improved CMI template to gather feedback and identify opportunities and challenges for implementation and other considerations. The workshop involved representatives from:

Project Sponsors

- Medicines Australia Regulatory Affairs Working Group
- The CMI Electronic Distribution Working Group

Government organisations

- The Therapeutic Goods Administration
- Health Direct

Industry

- Medicines Australia
- Generic Biosimilar Medicines Association
- Consumer Healthcare Products Australia (formerly Australian Self Medication Industry)

Consumers

- Consumers Health Forum of Australia
- Health Issues Centre

Health care professionals

- The Society of Hospital Pharmacists of Australia
- The Pharmaceutical Society of Australia
- The Pharmacy Guild of Australia
- GuildLink

Research insights

*What did we hear and observe from
participants during usability evaluation
sessions?*

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Findability (print and digital)

Across both streams, digital and print, the majority of participants expressed clear preference for the tested formats when compared with the original (current) CMI format – citing improvements in layout, navigation and readability.

Layout and style

Clarity of layout through reduced content density, use of bullet points, tabular content, clear heading hierarchies and section numbering all contributed to improved findability of content.

Index links and cross-referencing aided findability, as long as the link text clearly described the names of the sections they linked users to and didn't repeat generic text such as "see full CMI".

summary CMI vs Full CMI

Most participants saw value with the inclusion of the summary CMI, as an aid for easily understanding the structure of the document, and for navigation, but not as a stand-alone document.

As an aid to quick comprehension, a careful balance needs to be made between too little information (where the summary has little value and is bypassed) and too much (where participants incorrectly assume they have seen everything they need to).

I definitely think you're on the right track, it's a million times better.

Having fewer columns and bold headings helps make it really clear and easy to read.

The summary is good and quite concise, if I want more information I can click through to find it.

Findability (digital)

Digital vs print interaction differences

There are significant differences in the way people orient themselves with information in print vs digital.

Orientation to the overall document structure is much more intuitive when participants have a physical printed copy.

This orientation is not readily available in digital mediums, and best-practice navigation patterns should be used to aid findability. These could include tabs, menus, accordions, and other common methods for navigating information online¹.

Without navigation tools in the digital format, participants were easily disoriented through scrolling and jump-links within large amounts of text, and were more likely to miss important information.

Information architecture

Information was generally seen as being in logical places, though some participants had trouble finding information grouped by process (e.g. “Before using”, “While using”).

¹ Best practice design patterns evolve, sometimes quickly, and resources for best practice digital design and standards are numerous. Key resources for Australian Government digital services include:

- The Australian Government Digital Service Standard, <https://www.dta.gov.au/help-and-advice/about-digital-service-standard>
- The NSW Government Digital Design System, <https://www.digital.nsw.gov.au/digital-design-system>

With all the information in one place, if you need to know more, it's right here and you can click to open it.

If all you're looking for is information about hypoglycemia you should be able to go straight to it and not have to click a couple of links.

What's the difference between what should I know 'before' and 'while' taking Plavix?.

Comprehension (print and digital)

Plain English explanations

Participants were regularly confused by medical names, and medicine terms without explanation, or terms such as active vs inactive ingredients.

When plain English explanations or common examples were used to explain medical terms, users were better able to understand the meaning.

Very simple, descriptive to help people picture what they're looking for [vomit that looks like coffee grounds]

If lactose is an 'inactive' ingredient that means I can still take Plavix with a lactose allergy.

Product images

The inclusion of product images helped participants in their understanding of what the medicine was and how to use it – very clearly seeing its dosage form.

I can tell a lot about the medicine from the image, I can tell its an injectable and how many pens are in each pack.

External resources

If external resources are linked to in the digital format, then the URL needs to go directly to the specific instructions, – not the homepage of another website where the user is required to navigate further as this caused frustration in many participants.

In print format, this may be challenging for potentially long URLs or for users without internet, and alternative methods should be provided.

Actionability (print and digital)

Highlighting critical information

Important information, such as allergies and side effects was better understood when presented in simple tables, or when highlighted through bold text.

The levels of importance (e.g. less serious vs serious), and the urgency of the relevant action to be taken for each was more easily understood when highlighted using colour (e.g. red, tested in the digital format only).

Using red and bold to highlight emergency actions is very helpful because it catches your attention straightaway.

Warnings and precautions

Participants regularly expected important warnings about adverse reactions, contraindications, side-effects and allergies to be high up in the content order, and to be specific – not generic.

Many participants were not aware of the difference between the different types of potential adverse reactions, and having these elements in different parts of the document sometimes caused confusion as to their relative importance or relevance to them.

Allergies like lactose and gluten are very common and this information needs to be clear upfront in the document.

Consistency of calls-to-action

Phrases ‘talk to your doctor’, ‘check with your doctor, and ‘speak with your doctor’ caused confusion and made the relative importance and action required unclear. People expect a different action where different instructions are presented – even if none is intended.

There’s separate sections with these headings, what’s the difference between them?

Context of use (digital)

Accessing medicine information

Participants would more likely go to a health care professional, talk to friends or family, or search for information online if they had questions or concerns about their medicines.

Most participants had gone online to find health and medicines information.

No participant had previously come across a CMI online.

To find medicines information, participants would likely search for the information they want (in all cases would use Google).

Document format

Preference for either a digital or PDF document was dependent on context and how a person would use the information – and the same person may have different preferences depending on this context:

- Those who wanted to be able to access a physical copy of the CMI preferred a PDF version they could print.
- For first-use, or in-depth research, participants valued the digital interaction on the desktop.
- Participants would more likely use the mobile version 'on-the-go' for refreshing their knowledge of the document when required.

Trusted information sources

Participants trusted their GP or pharmacist to provide general information on medicines, as well as double check they could safely use the medicine.

However, not all participants had received this guidance when starting a new medicine.

Participants trusted government, but many were unaware of relevant online resources from the Government

Many would search for and evaluate information from 'less authoritative' sites, such as Wikipedia, Web MD, social forums and other sites found through Google search.

Some people would seek multiple information sources and form their own consensus.

Some participants exhibited distrust of pharmaceutical companies and would avoid their websites.

Quantitative user testing findings

The University of Sydney User Testing Stream




The following tables and explanatory notes provide a comparison of all three CMI documents evaluated in this study and the key high-level user testing findings.

Introduction

The following tables and explanatory notes provide a comparison of all three CMI documents evaluated in the print stream of the study, and the key high-level user testing findings.

Please see the results section in *Appendix F* for further information and explanation of these findings.

Key / legend

 Cells highlighted in green	<p>No major changes to the relevant section of the CMI are needed, because</p> <ul style="list-style-type: none"> At least 8 people within the cohort of 10 (or 9/11 for the Plavix® cohort) could find and understand the key information. This meant that the industry standard was met and the CMI worked well for this information.
 Cells highlighted in amber	<p>Some change(s) to the relevant section of the CMI are needed, because</p> <ul style="list-style-type: none"> Between 5 and 7 people within the cohort (8 for the Plavix® cohort) could find and understand the key information; and/or Participant feedback about, and their use of, the document indicated confusion or suboptimal document usability.
 Cells highlighted in red	<p>Changes to the relevant section of the CMI are needed, because</p> <ul style="list-style-type: none"> Less than 5 people within the cohort could find and understand the key information.

Key medicine information clearly communicated across *all* study CMI

Key medicine information	Plavix®	Ultibro®	Toujeo®
Indication for the medicine	✓	✓	✓
Disposal of medicine	✓	✓	✓
Less serious side effects	✓	✓	✓
Less serious side effects – action to be taken	✓	✓	✓
Drug-drug interaction	✓	✓	✓
Missed dose and action to be taken	✓	✓	✓

Key medicine information clearly communicated in *specific* study CMI

Key medicine information	Plavix®	Ultibro®	Toujeo®
Explanation – why doctor should be notified of upcoming surgery	✓	n/a	n/a
Storage	n/a	n/a	✓

n/a = not applicable

Key medicine information better communicated *as a result of changes made from the findings of the Plavix® CMI user testing*

Key medicine information	Plavix®	Ultibro®	Toujeo®
Stopping the medicine	!	✓	!
Use during pregnancy	!	✓	✓
Tests / monitoring before and/or during treatment with the medicine	!	✓	✓
Driving and using the medicine	!	✓	n/a

n/a = not applicable

Comparing usability across the CMI

- Although information advising to use the medicine until the doctor tells you to stop was included in the same Toujeo® CMI section (Section 4) in the summary and full CMI, it was not as direct (as Ultibro®) and not included in Section 5 where at least one participant was expecting to find the information.

Identified issues and key considerations for *tailoring the CMI template* to a specific medicine and dosage form

Key medicine information	Plavix®	Ultibro®	Toujeo®
Dosage of the medicine	✓	!	!

Comparing usability across the CMI

- The dosage for Plavix® was well found and understood by participants
- Although participants who user tested a CMI for a non-oral dosage form (Ultibro® and Toujeo®) could find and understand the relevant information for dosage, aspects about the dosage were unclear for several participants.
- It was not explicitly stated whether one capsule was the equivalent to one puff for Ultibro®. This information is included in the current CMI but not included in the EDWG-revised and user tested CMI. There was also a lack of directions for use of the device included in the full CMI.
- There was no specific dose of Toujeo® stated in the CMI; people were looking for a specific number / amount.

Identified issues and key considerations for *tailoring the CMI template* to a specific medicine and dosage form

Key medicine information	Plavix®	Ultibro®	Toujeo®
Existing allergy / allergy to ingredient	✓	!	✗

Comparing usability across the CMI

Ultibro® CMI

- Although the minimum number required were able to find and understand this information, there was a degree of difficulty seen within the cohort for this question. Active ingredients were not explained in Section 1 before the relevant action to be taken, if allergic, in Section 2 (as per the Plavix® full CMI). Together with the complicated / lengthy active ingredient names themselves, this meant that the second half of the bullet point was more likely to be missed. This is a content-specific issue rather than a format-specific issue.

Toujeo® CMI

- Toujeo® did not contain lactose, which was the allergy described in the given scenario. To answer the question, it was expected that participants were able to locate the ingredients under Section 7, and conclude that they would be able to use the medicine as it did not contain lactose.
- Many had difficulty with this question for Toujeo®.

Identified issues and key considerations for *tailoring the CMI template* to a specific medicine and dosage form

Key medicine information	Plavix®	Ultibro®	Toujeo®
Contraindication(s) / precaution(s) and action to be taken	!	✓	✓

Comparing usability across the CMI

- Information about what to do if you are already taking Plavix® and have upcoming surgery was located in Section 5 of the full CMI. People tended to find and focus on the warning information included under Section “2. What should I know before I take Plavix®?” instead.

Identified issues and key considerations for *tailoring the CMI template* to a specific medicine and dosage form

Key medicine information	Plavix®	Ultibro®	Toujeo®
Important or serious side effects and action(s) to be taken	✓	✓	✗
Explanation – why doctor should be notified of frequent hypoglycaemia	n/a	n/a	✗

n/a = not applicable

Comparing usability across the CMI

- For the Toujeo® CMI, the symptoms in the scenario given about important side effects and action(s) to be taken could be mapped to early symptoms of mild to moderate hypoglycaemia, which can be indicative of both suboptimal management of diabetes, and in this case, also a less serious side effect. Relevant information was therefore included in both Sections 5 and 6 on what to do if it is experienced.
- Participants required prompting to locate the relevant information under Section 5 of the heading. People generally expected this type of information to be found under Section 6 (6. Are there any side effects?). Once this information was found however, participants struggled to make the connection that they should also consider speaking to their doctor about this less serious side effect of mild to moderate hypoglycaemia. There were also other actions to be taken listed in Section 5 that may have confounded this e.g. make sure people close to you know how to recognise the symptoms of low blood sugar.

Quantitative user testing findings

The ThinkPlace Digital Stream

*The following table and explanatory notes
provide a comparison of all three CMI
documents evaluated in this stream.*

Comparative task success for the digital stream prototypes

Key medicine information	Plavix®	Ultibro®	Toujeo®
Indication for the medicine	✓	✓	✓
Dosage of the medicine	✓	✓	!
Existing allergy / allergy to ingredient	✗	!	!
Stopping the medicine	✓	✓	✗
Drug-drug interaction	✗	✓	✓
Important or serious side effects and action(s) to be taken	✓	✓	✗

Comparative tasks were given to participants in the digital stream. There were fewer participants in the digital stream (5 per CMI), so the results should be read with less confidence than the print stream.

The results did largely align, with one difference worth noting:

- Viewing the PDF online in the first round (Plavix®), where the content was displayed in two columns, meant participants largely missed information about ingredients and drug-drug interactions located in the second (right-hand) column of the PDF document – this supports observed behavior and recommendations for digital versions of CMI to use a single column.

Considerations and recommendations

*Recommendations for next steps, and
future considerations identified by
Industry and Stakeholders*

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Considerations

From the workshop, stakeholder representatives broadly endorsed the improved CMI template, and identified a number of considerations and priorities for implementation and future improvements.

Support for the changes

There was strong support within the group for the changes made to layout, style and information design of the printed document.

Representatives agreed the simplified summary page was an improvement to usability.

Implementation and transition

There was concern over the additional effort required to write a CMI summary.

Accurate product images on CMIs are difficult to maintain safely due to stock-flows and generic brand issues.

A desire for an updated and standardised lexicon and terminology.

A desire for the template to apply to over-the-counter (OTC) medicines.

A desire to harmonise approach with other markets, such as the EU.

Government coordination

Industry would need an industry-wide and coordinated transition plan.

There was a strong desire for any change and transition to be mandated by Government.

Desire for a strong digital direction

Stakeholders were excited by the direction of the digital prototype, and expressed a desire for a more comprehensive digital strategy for Consumer Medicine Information.

Health literacy and communication

Issues around consumer awareness and health literacy are much broader topics, that CMI is only a part of.

There was a desire to see a promotional campaign about CMI with consumers, pharmacists and health care professionals to raise awareness and encourage broader use.

Recommendations

Governance structure

Establish a governance structure and process for the implementation and review of CMI changes using the CMI template.

Facilitate stakeholder consensus

Achieve consensus on the wording of non-clinical content and content that is not medicine-specific, to be used consistently throughout all CMI documents.

Achieve consensus on the appropriate clinical content that needs to be included in the summary and full CMI.

Confirm the CMI subheadings most appropriate to use across different medicines / dosage forms / therapeutic classes.

User testing for all new CMIs

User test CMI developed using the CMI template to ensure clinical content is communicated effectively within the template format. Medicine users must be able to find and understand the key points of information relevant to their specific medicine.

Implementation roadmap

Work with industry to develop a coordinated transition plan for changing to the new format and to facilitate continuous improvement of CMIs, and harmonisation across jurisdictions.

Digital strategy for CMI

Develop with industry and stakeholders a strategy for digital CMI to:

- Leverage existing infrastructure like Health Direct and the My Health Record as distribution channels.
- Explore other channels for digital distribution, such as Voice (e.g. Alexa).
- Continue to design and test an optimal digital format/template.
- Develop a single-source of truth for all Consumer Medicine Information – be it a location online, or a central repository for data sharing.

Appendix A

The CMI print template

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[medicine name]*

Consumer Medicine Information (CMI) summary

Important information about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI).

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to

For more information, see Section [1. Why am I using \[medicine name\]?](#) in the full CMI.

2. What should I know before I use [medicine name]?

Do not use it if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you:

- have any other medical conditions
- take any medicines for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use \[medicine name\]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor or dentist you visit that you are using [insert medicine]. • [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly (if relevant). • [Insert other relevant key point(s)]
[Other relevant subheading(s)]	<ul style="list-style-type: none"> • [Note: this refers to any condition-specific or medicine-specific subheading(s) as per the full CMI] • [Insert other relevant key point(s)]
Driving or using machines	<ul style="list-style-type: none"> • Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	<ul style="list-style-type: none"> • Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	<ul style="list-style-type: none"> • Insert storage details, in particular any formulation-specific storage details e.g. refrigerate do not freeze • [Insert other relevant key point(s)]

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information on these side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

[medicine name]*

1

[medicine name]* (phonetic pronunciation – optional)

Active ingredient(s): [medicine active ingredient(s)] (phonetic pronunciation – optional)

Consumer Medicine Information (CMI)

This leaflet provides important information about using [medicine name]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].**

Where to find information in this leaflet:

1. [Why am I using \[medicine name\]?](#)
2. [What should I know before I use \[medicine name\]?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use \[medicine name\]?](#)
5. [What should I know while using \[medicine name\]?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using [medicine name]?

[medicine name] contains the active ingredient [insert active ingredient]. [medicine name] is [insert therapeutic class and explanation].

[medicine name] is used to [insert indication].

2. What should I know before I use [medicine name]?

Warnings

Do not use [medicine name] if:

- you are allergic to [active ingredient], or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- [insert other relevant contraindications].

Check with your doctor if you:

- have any other medical conditions [list any notable ones for the medicine / medical condition here]
- take any medicines for any other condition
- [insert specific precautions relevant to the medical condition].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

[Include any other relevant pregnancy information specific to the medicine].

[Relevant condition-specific or medicine-specific subheading(s)]

- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

[Options here include either:

- subdividing and listing the medicines depending on the nature of their interaction – an example of this is included below, or;

- tabulating these medicines that have been grouped according to the nature of their interaction, or;

- if there is only one list of medicines, then ensuring that the information is presented consistently.]

Some medicines may interfere with [medicine name] and affect how it works.

[Include an explanation of the nature of the interaction where possible] e.g.

Medicines that may increase the effect of [medicine name] include:

- [list medicines as appropriate]

Medicines that may reduce the effect of [medicine name] include:

- [list medicines as appropriate]

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].

4. How do I use [medicine name]?

How much to take / use

- [include relevant dosage information]
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

When to take / use [medicine name]

- [medicine name] should be used [insert as relevant].

How to [insert appropriate verb] [medicine name] (relevant for devices)

- [insert relevant step-by-step instructions / considerations for device use]

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also help to distinguish external links from internal document section links.

If you forget to use [medicine name]

[medicine name] should be used regularly at the same time each day [week or month]. If you miss your dose at the usual time, [insert appropriate explanation].

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- [include explanation of what "almost time for your next dose" refers to for the specific medicine where possible e.g. oral contraceptives]
- [include any other medicine-specific action and advice re missed dose, as appropriate]

If you use too much [medicine name]

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using [medicine name]?

Things you should do

[Include relevant action(s) and explanation(s)]

Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant action(s) to be taken]
- [include relevant statement(s) re action to be taken if the condition worsens / does not improve]

Remind any doctor or dentist you visit that you are using [medicine name].

Things you should not do

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant actions(s)]

[Relevant condition-specific or medicine-specific subheading(s)]

- Some medicines may require additional subheading(s) relevant to monitoring the condition and actions to be taken while on the medicine e.g. bleeding risk with antiplatelets / hypoglycaemia and what to do.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how [medicine name] affects you.

[medicine name] may cause dizziness in some people (or insert relevant information, as appropriate).

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may [insert effect relevant to use of the medicine].

Looking after your medicine

- [include device-specific storage information]
- [include storage information] e.g.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

[Include any specific information re discarding the medicine e.g. 28 day expiry from date of first use].

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

[medicine name]*

3

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]:</p> <ul style="list-style-type: none"> • [list as appropriate] <p>[Grouping 2 as per effect on body]:</p> <ul style="list-style-type: none"> • [list as appropriate] 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>[Insert appropriate action]</p>

Serious side effects

Serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]:</p> <ul style="list-style-type: none"> • [list as appropriate] <p>[Grouping 2 as per effect on body]:</p> <ul style="list-style-type: none"> • [list as appropriate] 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

[medicine name]*

7. Product details

This medicine is only available with a doctor's prescription.

What [medicine name] contains

Active ingredient (main ingredient)	[insert]
Other ingredients (inactive ingredients)	[insert]

Do not take this medicine if you are allergic to any of these ingredients.

What [medicine name] looks like

[medicine name] is... (Aust R XXXXXX).

Who distributes [medicine name]

[insert sponsor name and contact details]

This leaflet was prepared in [insert month and year].

Appendix B

The CMI digital prototype

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Digital prototype – default view

Toujeo* (too-jay-oh)
Consumer Medicine Information (CMI)

Important facts you need to know about your medicine

This page provides important information about using Toujeo. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or queries about using Toujeo.



Information on this page:

1. Why am I using Toujeo?
2. What should I know before I use Toujeo?
3. What if I am taking other medicines?
4. How do I use Toujeo?
5. What should I know while using Toujeo?
6. Are there any side effects?
7. Product details

1. Why am I using Toujeo?

Toujeo is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

▼ Show details

2. What should I know before I use Toujeo

Do not use it if you have ever had an allergic reaction to insulin.

Talk to your doctor if you:

- have diabetic ketoacidosis (often caused by high blood sugar levels)
- have any other medical conditions, including kidney problems or liver problems
- take any medicines for any other medical condition.
- are pregnant or plan to become pregnant or are breastfeeding.

▼ Show details

3. What if I am taking other medicines?

Some medicines may interfere with Toujeo and affect how it works.

▼ Show details

4. How do I use Toujeo?

- Toujeo should be injected under the skin. Your doctor will tell you when and how much Toujeo you need to use each day.
- A video providing information on how to inject Toujeo is available at: www.simple-steps.com.au/tf
- Your doctor may change your dose, depending on your blood sugar levels.
- Use Toujeo until your doctor tells you to stop. Too much or too little insulin can cause serious effects.

▼ Show details

5. What should I know while using Toujeo?

Things you should do	<ul style="list-style-type: none"> • It is very important that you manage your diabetes carefully. • Measure your blood sugar level regularly. • Tell your doctor if you often have low blood sugar levels or have ever become unconscious after using Toujeo. • Always carry sugary food or drink with you in case you start to have any symptoms of low blood sugar. • Remind any doctor or dentist you visit that you are using Toujeo.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Drinking alcohol may mask the symptoms of low blood sugar.
Looking after your medicine	<ul style="list-style-type: none"> • Keep unopened Toujeo pre-filled pens in the fridge where the temperature is between 2-8°C. Do not freeze. • Before using a new pre-filled pen, take it out of the fridge and let it come to room temperature for 1-2 hours. • After you have started using a pre-filled pen, do not put it back in the fridge. Keep it at room temperature below 30°C, away from direct heat and light. • Discard within 28 days any pre-filled pen you have started using or any spare pen taken out of the fridge.

▼ Show details

6. Are there any side effects?

Serious side effects may include low blood sugar (hypoglycaemia) or an allergic reaction.

For more information on these side effects and what to do if you have any side effects, click show details.

▼ Show details

7. Product details

This medicine is only available with a doctor's prescription.

▼ Show details

This leaflet was prepared in May 2019.

- Index menu for orientation and quick access.
- Panels showing CMI summary information – expandable for full detail.
- Single column for easier reading on screen
- Responsive design – same document adapts to screen size on mobile.
- Digital distribution should make product images easier to update.

Toujeo*

Consumer Medicine Information (CMI)

Information on this page:

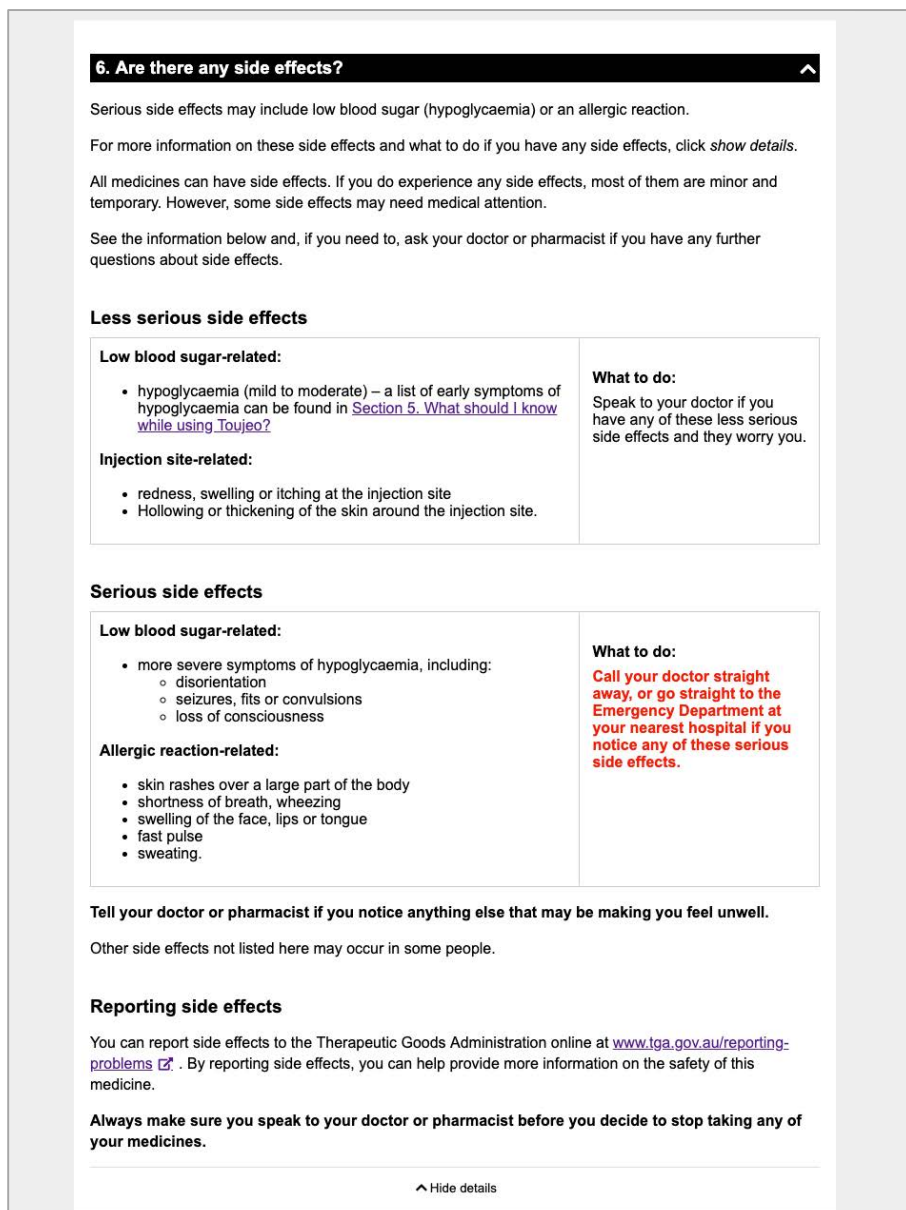
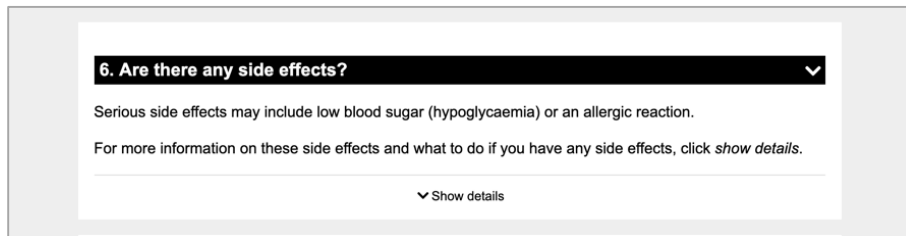
1. [Why am I using Toujeo?](#)
2. [What should I know before I use Toujeo?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Toujeo?](#)
5. [What should I know while using Toujeo?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Toujeo?

Toujeo is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

▼ Show details

Digital prototype – expanded view



- Showing full detail of CMI for specific section by expanding the summary CMI.
- Digital format using colour to show critical actions.

Appendix C

CMI writing guide

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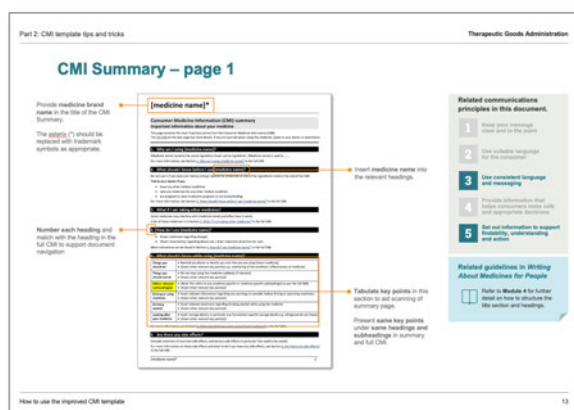
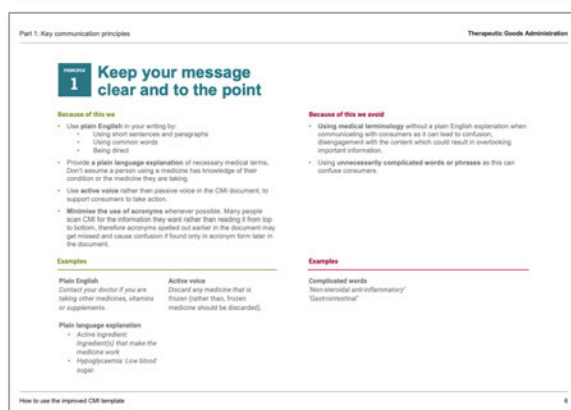
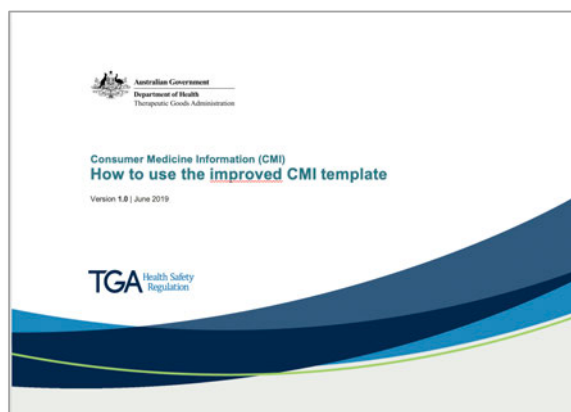


CMI Writing Guide

Accompanying this report is a guide that outlines how to use the improved CMI template when writing CMI. It is intended as a quick reference only.

The guide is called **Consumer Medicine Information (CMI): How to use the improved CMI template**

This complements the existing *Writing about medicines for people: Usability Guidelines for Consumer Medicine Information, 3rd edition* by David Sless and Ruth Shrensky, which contains more detailed guidance on how to communicate with consumers of CMI documents.



Appendix D

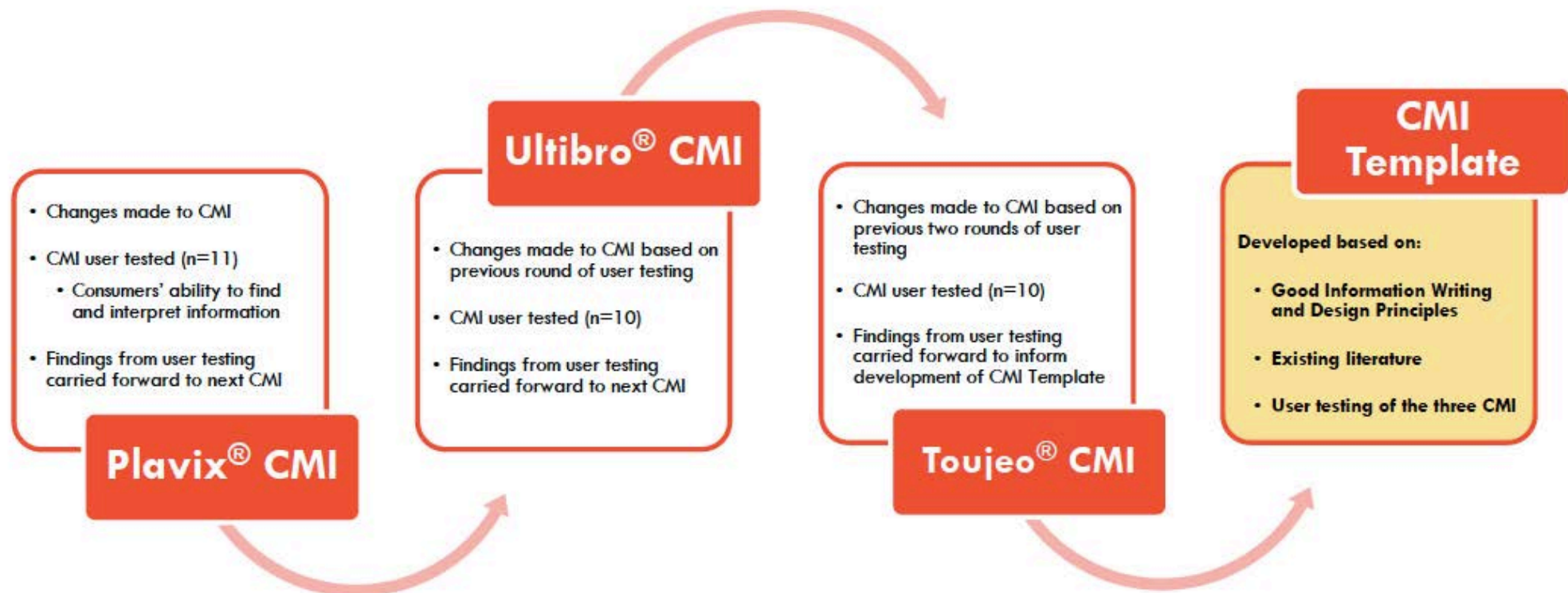
*The University of Sydney user testing
interview session process*

TGA Health Safety
Regulation

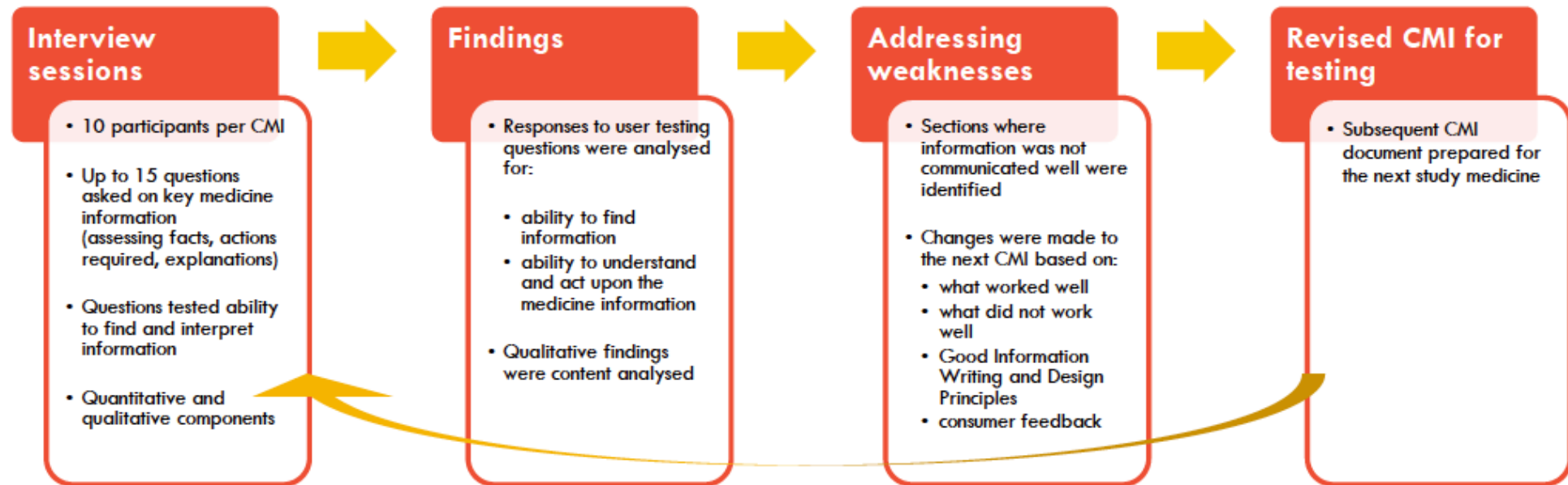


The University of Sydney User Testing Stream

Overview of Iterative Process of User Testing and Design of CMI



The University of Sydney User Testing Stream – User Testing Interview Session Process



Key Medicine Information underpinning the User Testing Questionnaire

- Indication for the medicine
- Dosage, including the use of the device (inhaler and insulin injection)
- Existing allergy/allergy to ingredient
- Disposal of medicine
- Common/less serious side effects and important side effects
- Contraindication(s)/precaution(s)
- Drug-drug interaction(s)
- Missed dose and what to do
- Driving when taking the medicine
- Stopping the medicine
- Use during pregnancy
- Tests/monitoring before and/or during medicine taking
- Storage

Participants

- ≥ 18 years
- English skills sufficient to take part in the study
- Not on the study medicine or a medicine in the same class
- Not a healthcare professional
- Not visually or cognitively impaired
- Not participated in user testing in the past 6 months

Demographically matched participant cohorts for each CMI tested

- **Age:** at least 1 in each decade between 30 and 70+ years
- **Sex:** minimum of 3 per sex
- **Education:** no more than 3 higher education graduates
- **Written information use:** at least 2 who either do not regularly use written documents as part of their work, or who are currently not working or retired

User testing method

The user testing method used was based on the process developed by Sless et al.

(Sless D, Shrensky R. Writing about medicines for people: usability guidelines for Consumer Medicine Information. 3rd ed. Sydney: Australian Self Medication Industry; 2006)

Ethics approval

This study was approved by The University of Sydney Human Research Ethics Committee (project number 2019/122).

Appendix E

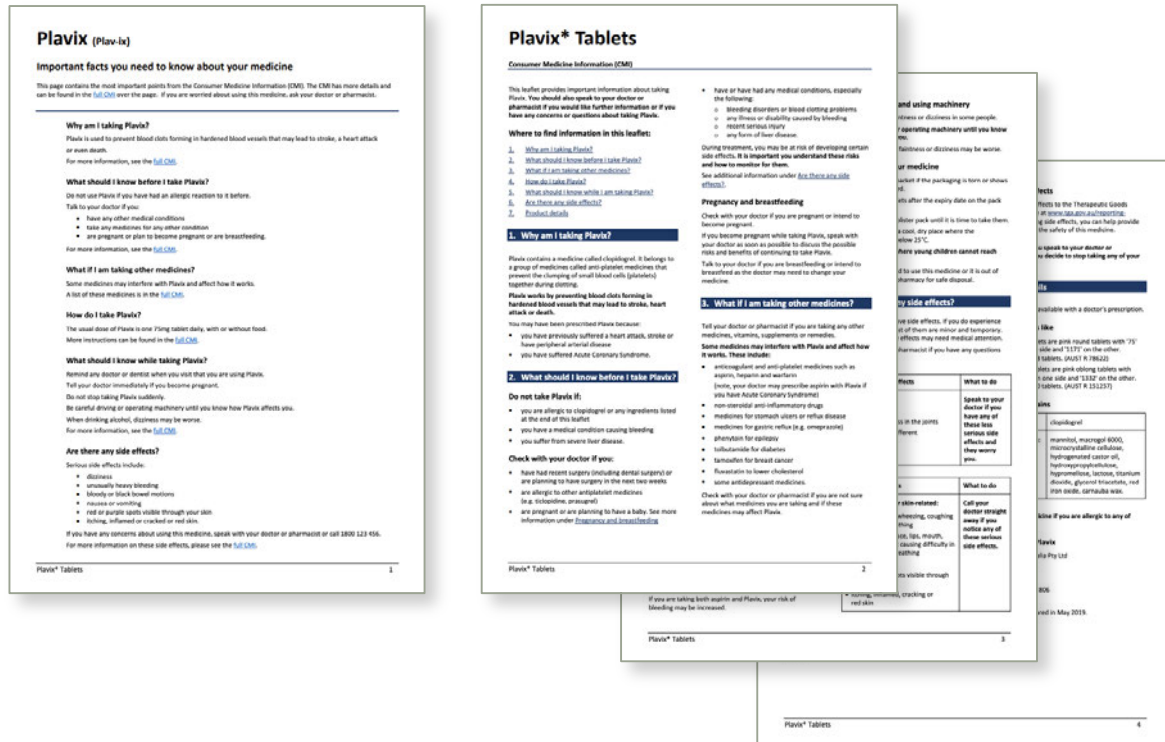
Design iterations and usability reports

TGA Health Safety
Regulation



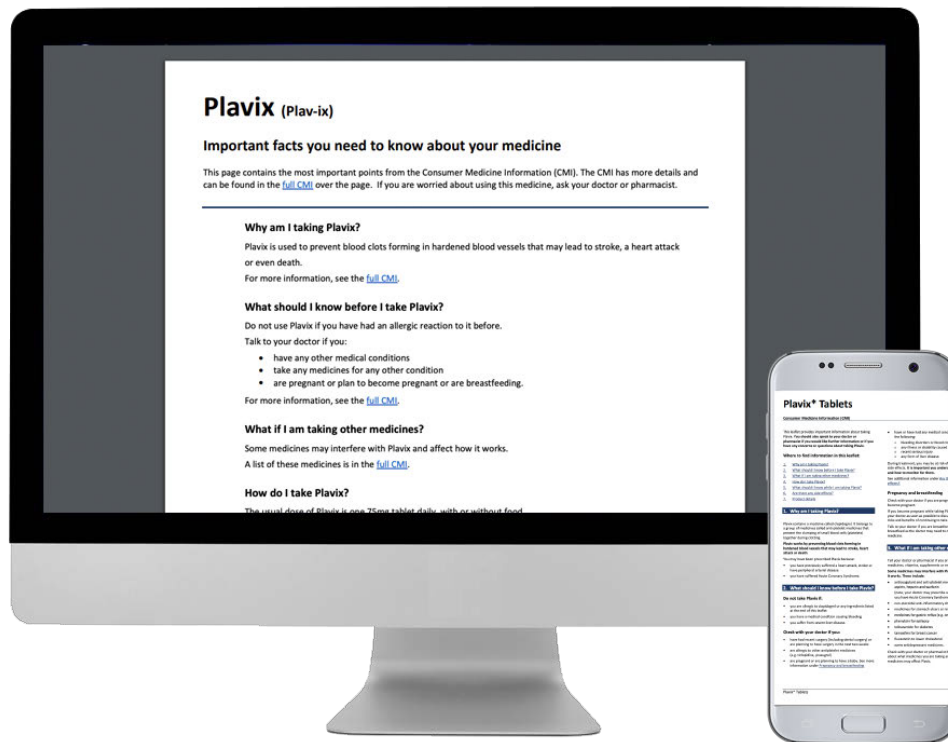
Week 1: Plavix®

Plavix® CMI (print)



- Participants liked that the headings were clearly presented and the use of colour.
- Information was in general in a logical place, and participants found it easy to understand.
- Participants liked side effects grouped and tabulated – made the information easier to digest.
- In general, people liked the concept of a summary page and found it useful; however, for the most part, people said that it would not be enough to be given on its own as a one page document.
- The majority preferred the revised format over the current format (the current CMI format was perceived to be overwhelming to read, a lot of information, and not as user-friendly).

Plavix® CMI (digital PDF)



- The updates were a clear improvement from the current.
- The overall document, headings and sections were clearly laid out and in a logical order.
- Participants had difficulties due to a lot of scrolling and trial and error.
- The summary page did not surface enough value to participants – some was seen as too generic.
- Generic and repetitive links (Full CMI) were not well-used for navigation.
- Multiple columns made it easy to miss content online – especially on mobile.
- Allergy information was difficult to find as they did not associate this with the list of ingredients.
- There was often confusion between section 2 and 5 (What should I know before/while?).
- Participants expected to see an image of the medicine.
- Participants were able to easily understand key information when explained in plain English or described using common examples.
- Some of medical language was complex and not well explained, such as 'active' and 'inactive' ingredients and 'non-steroidal anti-inflammatory'.

Changes for week 2

High-level changes for both streams

- Using bullet points and additional sub-headings to ensure important information stands out in sections.
- Numbered headings in the summary CMI, also formatted consistently with the full CMI.
- Ensuring consistency in location and expression of information between summary page and full CMI.
- Expressing active and inactive ingredients using alternate terms.
- Introduction product image to 'Product details' section.
- Instead of links titled 'full CMI', the full section names were used in the link e.g. '4. How do I use Plavix?'
- Use tables for other actionable information beyond just side-effects to improve content findability e.g. Section 5 on the summary CMI page.

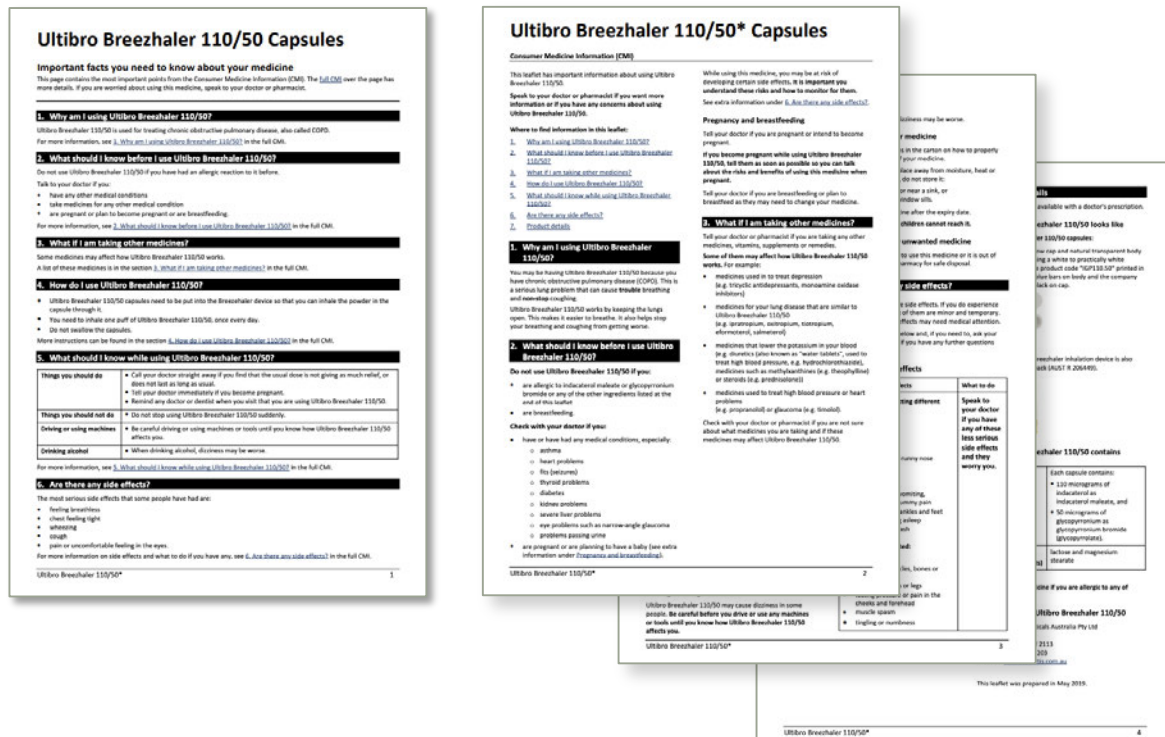
Digital specific changes

- Shift to single column format for HTML.
- Narrowing the width of the screen on desktop to a regular field of vision.
- Separation of summary page and full CMI where participants could navigate between them.
- Highlighting important information in red to draw attention to actions required.

Please see Table 2 in Appendix F for further details regarding the key changes relevant to CMI template development that were implemented for the print CMI versions revised by The University of Sydney research team.

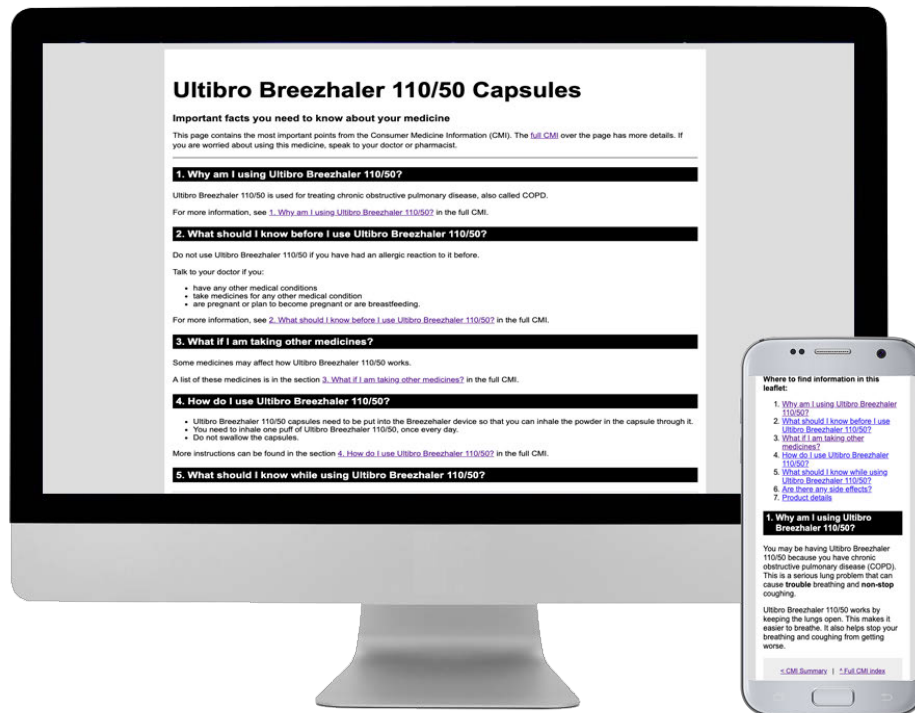
Week 2: Ultibro®

Ultibro® CMI (print)



- Participants liked the clear headings and black banded headings.
- Information was in general in a logical place / order, and participants found it easy to understand (as per previous findings).
- As per the previous round, participants liked side effects grouped and tabulated.
- In general, people liked the summary page and found it useful; some said that it would not be enough to be given on its own as a one page document.
- A few participants did state that having the summary page alone would be sufficient as there were links to the full CMI that could be used as needed.
- Links in the document signaled that this document was designed to be used in an online / electronic format.
- Whilst several queried the usefulness of a link for those who are not as computer literate, others who may have accessed information online more regularly were comfortable with it.
- The majority preferred the revised Ultibro® CMI format over the current Ultibro® CMI format.

Ultibro® CMI (digital HTML)



- Navigation was improved by using the descriptive links on the summary page (instead of 'full CMI').
- More participants were able to scan the side effects easily in a single table.
- Participants still lost orientation when navigating between the summary and full CMI.
- Scrolling and repeated content made it hard to orient within the full CMI.
- Continued confusion between sections 2 and 5 (What should I know before/while?)
- Participants found the added image of the medicine useful to understand what it looked like.
- Highlighting critical information aided recognition of its importance.
- Some complex terminology continued to cause problems - 'active' and 'inactive ingredients' and medicine category information.
- There was some confusion about dosage and whether one capsule was the equivalent of one dose.
- Some participants continued to be unclear if they could take this medicine if they had a lactose allergy.

Changes for week 3

High-level changes for both streams

- Reduce repetition where possible
- Include image of medicine on summary page
- Retain explanations for consequences of not following actions
- Continue to group side effects according to effect on the body, specific to the medicine as per previous rounds

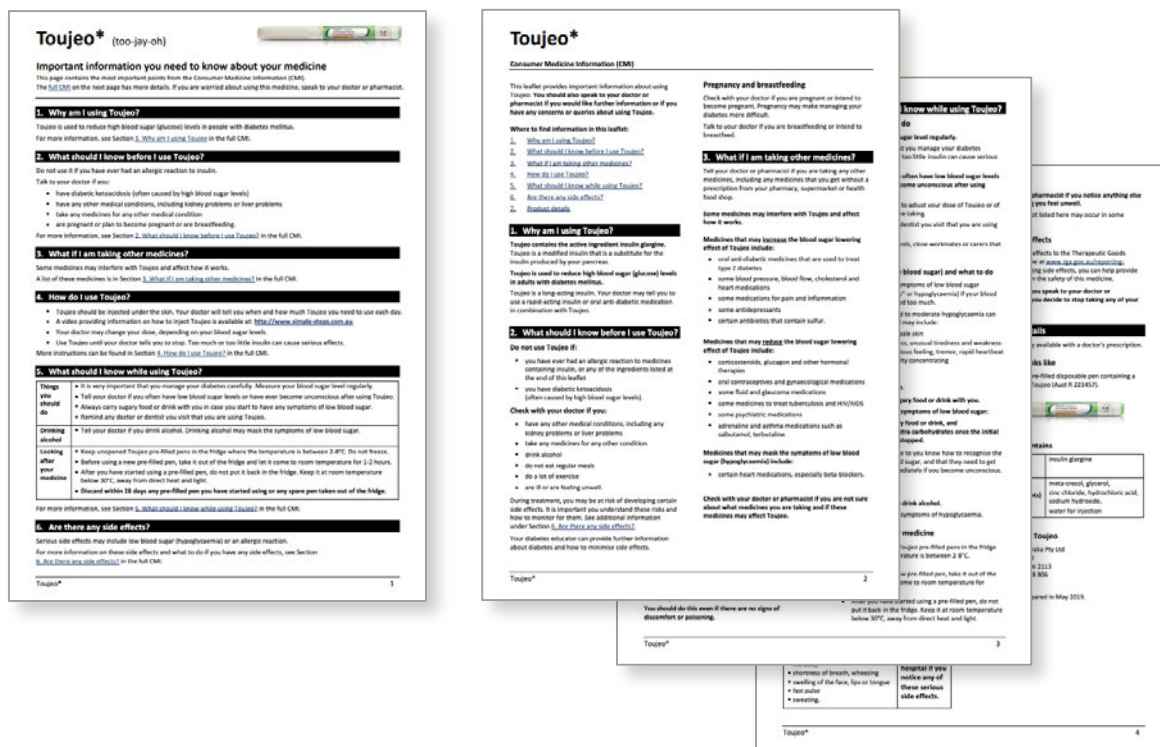
Digital specific changes

- Combine summary page and full CMI by making the HTML design expandable and collapsible to view more or hide information as needed
- Introduce product image near medicine title
- Provide plain English explanations for 'active' and 'inactive' ingredients
- Place index links at the top of the document to aid navigation
- Introduce table to Section 3. What if I am taking other medicines

Please see Table 2 in Appendix F for further details regarding the key changes relevant to CMI template development that were implemented for the print CMI versions revised by The University of Sydney research team.

Week 3: Toujeo®

Toujeo® CMI (print)



- Participants felt there was a lot of information; some were overwhelmed – on occasion, people could remember they had read a particular point somewhere but had significant difficulty finding it again.
- Clear headings continue to be liked, as well as numbered headings.
- As per the previous round, participants generally liked side effects grouped and tabulated.
- Mixed opinions on the summary page for the Toujeo® e.g. it was liked as a summary to refer to; could just be replaced with the table of contents.
- More participants in this round preferred the existing CMI format over the tested CMI format, compared with the previous user testing rounds.
- On the whole, there were mixed opinions about the level of detail / content needed; interestingly, people would like more information in some instances.
- There were mixed opinions about the level of detail required for directions for use for a device in a CMI and whether a video was enough.

Toujeo® CMI (digital HTML)



- The combined summary and full CMI in expandable and collapsible format improved navigation and orientation through the document.
- Participants found value in the upfront placement of the medicine image and were able to find key information from it.
- Placement of index links at the top of the summary helped navigation.
- Some summary panels had too much information visible, leading some users to think there was nothing more to find (e.g. Section 5).
- When all panels open, similar orientation and scrolling issues were seen.
- Continued issues for many on labelling/grouping (e.g. Sections 2 and 5, Allergy information in Section 7).
- Complex terminology caused problems when unsupported by plain English explanation (e.g. Insulin glargine, diabetes mellitus and ketoacidosis).
- Plain English explanations for 'active' and 'inactive' ingredients helped with understanding.
- Inconsistent instructions - 'talk to your doctor', 'check with your doctor, and 'speak with your doctor' made actions unclear.
- Participants expected calls-to-action to be situated at the start of each section or sub-section.

Appendix F

The University of Sydney research report

TGA Health Safety
Regulation



User testing and development of a new Consumer Medicine Information (CMI) template

Professor Parisa Aslani

Dr Vivien Tong

The University of Sydney School of Pharmacy

Faculty of Medicine and Health

The University of Sydney

June 2019

The following document has been prepared for inclusion as an Appendix in the report “Usability evaluation of Consumer Medicine Information (CMI) documents”.

The document outlines the study background, aims, methods, main quantitative findings, high-level qualitative findings, and future directions and recommendations that stemmed from The University of Sydney User Testing Stream.

Please see the resulting publication(s) from this work once available for further context, detail and elaboration of the study and its findings.

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1. Background

Consumer Medicine Information (CMI) are leaflets which are produced for all prescription medicines and over-the-counter (or non-prescription) Pharmacist Only medicines in Australia.¹ By adopting a standardised format, the CMI format is intended to assist consumers in navigating and finding information that they need about their medicines. However, there has been criticism of the current CMI formats, as documented in previous research findings² as well as recent debate seen in the Australian media.³

Previous research developed and evaluated alternative CMI formats and demonstrated that the current CMI formats can be improved whilst still ensuring that the leaflet itself meets all legislative requirements, and also used more frequently by pharmacists and consumers.² However, despite the Investigating Consumer Medicine Information (I-CMI) project² being conducted approximately 10 years ago, the adoption and widespread implementation of the research findings has been limited in terms of these alternative CMI formats.

This study, therefore, aimed to build on the alternative CMI formats from the I-CMI project, as well as the evidence from the literature, and develop one format as a template that could be used for future implementation within the Australian context by the Therapeutic Goods Administration (TGA).

2. Study aim and objectives

Aim

To develop one evidence-based CMI format that could be implemented as a CMI template within the Australian context by the TGA.

Objectives

1. To develop and user test three Consumer Medicine Information (CMI) formats intended to be used as potential templates for future implementation within the Australian context.
 2. To explore consumer perspectives on these formats and consumers' perceived acceptability for their widespread use in Australia.
-

3. Methods

3.1 Research study stages

The University of Sydney research stream for this study had the following key research stages:

1. Review and revision of CMI formats provided by the CMI Electronic Distribution Working Group (EDWG)
2. User testing evaluation of final CMI
3. Data analysis and recommendations

3.2 Review and revision of CMI formats provided by the CMI Electronic Distribution Working Group

3.2.1 CMI documents that were evaluated

Three existing CMI leaflets were reviewed and modified using good information writing and design principles,^{2, 4-6} in order to develop CMI that are easy to use and understand by consumers with low health literacy.

The chosen study medicines were:

- Plavix® (clopidogrel)
- Ultibro® Breezhaler® (indacaterol; glycopyrronium)
- Toujeo® (insulin glargine)

Collectively, these medicines represented three different dosage forms and delivery methods, which allowed for varying aspects relevant to CMI to be further explored in the study.

The stepwise approach implemented for review and revision of the CMI was as follows:

1. Plavix®, Ultibro® and Toujeo® CMI were developed by the CMI EDWG based on the CMI templates from the Investigating Consumer Medicine Information (I-CMI) study,² which was funded through the Australian Department of Health and Ageing.
 - The I-CMI study had developed, consumer user-tested, and pilot tested several CMI templates in community pharmacy with pharmacists and patients / consumers (receiving the actual medications – Lipitor® (Schedule 4 or prescription medicine) and Mersyndol® (Schedule 3 or Pharmacist Only (over-the-counter) medicine)).
2. The CMI EDWG-developed Plavix®, Ultibro® and Toujeo® CMI documents were then reviewed by the TGA, and changes made. Most of these changes were implemented in the CMI documents (Table 1). Reasons for not implementing any of the proposed changes have been provided in Table 1.

3. The TGA-revised Plavix®, Ultibro® and Toujeo® CMI documents were then reviewed by Professor Parisa Aslani and Dr Vivien Tong, The University of Sydney (USYD), who have extensive experience in the field, and changes made based on:

- Good Information Writing and Design Principles, including information from the following sources:
 - I-CMI Report²
 - Raynor and Dickinson⁵
 - Sless and Shrensky⁴
 - CDC guidelines on writing information⁶

It should be noted that a comprehensive review and changes of clinical content specific to the medicine for each CMI was not conducted.

4. The USYD-revised Plavix®, Ultibro® and Toujeo® CMI documents (print versions) were user tested by The University of Sydney team.
5. The usability of the USYD-revised Plavix®, Ultibro® and Toujeo® CMI documents (digital versions) were evaluated by the ThinkPlace team.
6. An iterative revision process was also adopted, whereby The University of Sydney (USYD) team revised the Ultibro® CMI primarily based on the USYD consumer user testing quantitative findings of Plavix®; and the USYD team next revised the Toujeo® CMI primarily based on the USYD consumer user testing quantitative findings of Plavix® and Ultibro®.

See Table 1 and Table 2 on the following pages for more detailed information on the changes made to the CMI documents. Table 2 summarises the key changes that are pertinent for CMI template development.

Table 1. Summary of the TGA proposed changes to the three evaluated CMI and decisions made for their implementation prior to user testing

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Summary page	<ul style="list-style-type: none"> “Important facts you need to know about your medicine” to be stated in all uppercase letters 	Not implemented	n/a (already in all uppercase from original EDWG version – Not implemented)	Not implemented	Text stated using all uppercase letters makes it more difficult to read; extensive use of uppercase should be avoided.
	<ul style="list-style-type: none"> “Tablets” to be specified in title / medicine name as the title on the summary page 	n/a	Not implemented	n/a	The formulation is capsules (for inhalation) not tablets.
	<ul style="list-style-type: none"> “TOO-JAY-OH” to be stated in all upper case: 	n/a	n/a	Not implemented	Text stated using all capitals makes text more difficult to read; extensive use of uppercase was avoided. N.B. Plavix® had the phonetic spelling in all uppercase; A point of difference was that Toujeo® phonetic spelling was included in sentence case. The impact of this was not specifically evaluated in the user testing.
Summary page subheading: 1. Why am I taking / using [medicine name]?	<ul style="list-style-type: none"> Minor grammatical error to be changed to “see <u>the</u> full CMI” 	Implemented	Implemented	Implemented	Minor and appropriate change.
	<ul style="list-style-type: none"> Underlined text to be inserted in: “Ultibro Breezhaler 110/50 tablets, <u>which are put into and inhaled through the Breezehaler device</u>, is used for treating chronic obstructive pulmonary disease, also called COPD.” 	n/a	Not implemented	n/a	The formulation is capsules (for inhalation) not tablets. The detail about the use of the device / insertion of capsules for inhalation lengthens the sentence and is not the most appropriate information for this section. This information was better suited for the section “4. How do I use Ultibro Breezhaler 110/50?”.
Summary page subheading: 2. What should I know before taking / using [medicine name]?	<ul style="list-style-type: none"> Lower case to be used for the word doctor in “Talk to your Ddoctor if <u>you</u>.” and the word “you” to be deleted from the beginning of each listed bullet point below to reduce repetition 	Implemented	Implemented	Implemented	Reduced repetition may assist with reducing reader burden. The suggested change improves sentence flow.
	<ul style="list-style-type: none"> Minor grammatical error to be changed to “see <u>the</u> full CMI” 	Implemented	Implemented	Implemented	

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Summary page subheading: 3. What if I am taking other medicines?	<ul style="list-style-type: none"> “A list of these medicines is in the full CMI.” to replace “For more information, see full CMI” 	Implemented	n/a (already included in original EDWG version)	Implemented	This change provides more specificity regarding what can be found in the relevant CMI section.
	<ul style="list-style-type: none"> “on you” to be deleted from the end of the sentence “Some medicines may interfere with Toujeo® and affect how it works on you.” 	n/a	n/a	Implemented	Consistent wording with other CMI.
Summary page subheading: 4. How do I take / use [medicine name]?	<ul style="list-style-type: none"> “Detailed instructions can be found in the full CMI.” to replace “For more information, see full CMI” 	Partially implemented	n/a (already included in original EDWG version N.B. Similar revision made to Ultibro® CMI as proposed for Toujeo®)	Partially implemented	The CMI formats for the devices lack detailed stepwise instructions for device use. For the purposes of developing a standard CMI template, minor rewording has been suggested to reflect that not all detailed instructions are included in the CMI i.e. detailed device use instructions need to be accessed by the person via a link. Partial implementation – suggested rewording to: “More instructions can be found in the full CMI” (Plavix® CMI) “More instructions can be found in the section 4. How do I use Toujeo? In the full CMI” (Toujeo® CMI)
	<ul style="list-style-type: none"> Minor grammatical change: “here” to be deleted 	n/a	Implemented	n/a	
Summary page subheading: 5. What should I know while taking / using [medicine name]?	<ul style="list-style-type: none"> Lower case to be used for “D<u>o</u>ctor” and “D<u>o</u>dentist” for consistency 	Implemented	n/a (already included in original EDWG version)	n/a (see below)	
	<ul style="list-style-type: none"> Minor grammatical error to be changed to “see <u>the</u> full CMI” 	Implemented	Implemented	Implemented	
	<ul style="list-style-type: none"> “<u>Remind any doctor or dentist when you visit that you are using Toujeo.</u>” to be included 	n/a (similar statement already included in original EDWG version)	n/a (similar statement already included in original EDWG version)	Implemented	

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Summary page subheading: 6. Are there any side effects?	• Lower case to be used for side effects	Implemented	n/a (already included in original EDWG version)	n/a (already included in original EDWG version)	
	• Lower case to be used for “ <u>D</u> octor” and “ <u>P</u> harmacist” for consistency	Implemented	n/a (already included in original EDWG version)	n/a	
	• Suggested rewording to: “For more information <u>on these side effects</u> , please see the full CMI below.”	Implemented	Implemented	Implemented	
	• “low blood sugar” to be included as an explanation for term hypoglycaemia	n/a	n/a	Implemented	
Beginning section of full CMI	• Suggested printing of medicine name in all uppercase letters	Not implemented	n/a (already in all uppercase from original EDWG version – not implemented however)	n/a (already in all uppercase from original EDWG version – not implemented however)	All uppercase letters to be avoided in good information design as it is harder to read; suggested reverting to what the current CMI implements i.e. Plavix® Tablets.
	• “(too-jay-oh)” to be deleted	n/a	n/a	Implemented	No significant impact on the content as the pronunciation is included on the summary page
Full CMI: 1. Why am I taking [medicine name]?	• Suggested inclusion of: “This medicine is only available with a doctor's prescription.”	Partially implemented	Partially implemented	Partially implemented	This information has been moved to under the heading “7. Product details” as this is a more appropriate location for this statement within the CMI.
	• “Periodic worsening of” to replace “from getting worse from time to time”	n/a	Not implemented	n/a	“Periodic worsening of” is not plain English; original wording was therefore retained.
	• “your” to be included in “Produced by <u>your</u> pancreas”	n/a	n/a	Implemented	
	• “rapid-acting”	n/a	n/a	Implemented	

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Full CMI: 2. What should I know before taking [medicine name]?	<ul style="list-style-type: none"> Full stop to be included at the end of last bullet point in subsection / list 	Implemented	Implemented	Implemented	<u>Note:</u> Question mark added at the end of “Are there are any side effects?” for consistency with the complete section heading.
	<ul style="list-style-type: none"> “Check with your doctor if <u>you...</u>” and “you” to be subsequently deleted at the start of each corresponding bullet point 	Implemented	n/a (already included in original EDWG version)	n/a (this was not recommended as a change for the Toujeo® CMI)	
	<ul style="list-style-type: none"> Link name to be replaced with full corresponding section name (“Are there any side effects?” instead of “side effects” only) 	Implemented	Implemented	n/a (already included in original EDWG version)	
	<ul style="list-style-type: none"> “Pregnancy and Bbreastfeeding” to be stated in sentence case 	Implemented	Implemented	n/a (already included in original EDWG version)	
	<ul style="list-style-type: none"> Brackets to be included around “(listed at the end of this leaflet)” and “these are” to be deleted from the start of this sentence 	n/a	Partially implemented	n/a	Formatting of this statement retained as per Plavix® CMI for consistency.
	<ul style="list-style-type: none"> “Conditions” to replace “problems” 	n/a	Implemented	n/a	Consistent wording.
	<ul style="list-style-type: none"> “this medicine” to replace full medicine name 	n/a	Implemented	n/a	Simplification / use of less words.
	<ul style="list-style-type: none"> “the doctor” to be replaced with “the” 	n/a	Implemented	n/a	Simplification / use of less words.
	<ul style="list-style-type: none"> Lower case to be used for all bullet points (rather than sentence case) 	n/a (already included in original EDWG version)	n/a (already included in original EDWG version)	Implemented	
	<ul style="list-style-type: none"> “sugar” to replace “glucose” 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> Minor rewording for the sentence “Your diabetic educator will also can provide you with further information about diabetes, and how to minimize minimise side effects side effects.” 	n/a	n/a	Implemented	N.B. “diabetic educator” was revised to “diabetes educator” prior to user testing.

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Full CMI: 3. What if I am taking other medicines?	<ul style="list-style-type: none"> Minor reformatting of sentence about concomitant use of aspirin and clopidogrel in ACS (brackets around sentence and replacement of colon with comma) 	Implemented	n/a	n/a	
	<ul style="list-style-type: none"> Full stop to be included at the end of the last bullet point in the subsection 	Implemented	Implemented	Implemented	
	<ul style="list-style-type: none"> “Breezhaler 110/50” to be included after Ultibro 	n/a	Implemented	n/a	Consistent wording of medicine name.
	<ul style="list-style-type: none"> Hyphen to be included in “anti-diabetic” 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “low blood sugar” to be included as an explanation for term hypoglycaemia 	n/a	n/a	Implemented	
Full CMI: 4. How do I take [medicine name]?	<ul style="list-style-type: none"> Question mark to be included at the end of the subheading: “How to take?” / “How to use?” 	Not implemented	n/a	n/a (already included in the original EDWG version – not implemented however)	The section heading itself is already formatted as a question. For consistency, all subheadings are formatted as statements.
	<ul style="list-style-type: none"> The word “not” to be in uppercase in “Do <u>NOT</u>” 	Not implemented	Not implemented	n/a (already included in the original EDWG version – not implemented however)	Using uppercase for the word “not” in this direction is inconsistent with other directions included in the CMI. Furthermore, the statement is already bolded therefore it is important to place emphasis on the entire direction rather than just the word “NOT”.
	<ul style="list-style-type: none"> Under the “If you take too much (overdose)” subheading, suggested re-ordering of action to be taken as contact the doctor first, then call Poisons Information Centre and then Emergency department 	Not implemented	Not implemented	Not implemented	By recommending to contact the doctor first, this may be interpreted as the first action the person needs to consider if an overdose has happened. The existing / similar order should be retained so as to ensure the person consecutively considers contacting each relevant source / health care provider. This may then in turn help ensure access to immediate, relevant and expert medical advice and minimising unnecessary delays to life-saving care.
	<ul style="list-style-type: none"> “<u>go to the Emergency Department at your nearest hospital</u>” to replace “or nearest hospital” 	n/a (already included in original EDWG version)	n/a (already included in original EDWG version)	Implemented	This is consistent with the Plavix® and Ultibro® CMI. Furthermore, as an injectable insulin, emergency medical attention may be required and this equates to a safer action to be taken which is in line with the very serious side effects.

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
	<ul style="list-style-type: none"> The word and link associated with “here” to be replaced with the full URL 	n/a	Implemented	n/a	This allows the person who is accessing the CMI in paper-based format to type in the relevant URL into their browser to access the additional information.
	<ul style="list-style-type: none"> “health care professional” to be replaced with “pharmacist” in the statement: “If you miss a dose and aren’t sure what to do, contact your doctor or <u>pharmacist</u> health care professional for specific advice.” 	n/a	n/a	Implemented	The specific reference to pharmacist is needed for Toujeo® as there is minimal directions given in the CMI for what to do if a dose is missed.
Full CMI: 5. What should I know while I am taking [medicine name]?	<ul style="list-style-type: none"> Full stop to be included at the end of last bullet point in subsection 	Implemented	Implemented	Implemented	
	<ul style="list-style-type: none"> Full stop to be included at the end of the sentence 	Implemented	Implemented	n/a	
	<ul style="list-style-type: none"> Statement regarding safe disposal to be reworded to: “If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.” 	Implemented	Implemented	Implemented	
	<ul style="list-style-type: none"> “in the bathroom or near a sink” and “in the car or on window sills” to be bullet pointed 	n/a	Implemented	n/a	
	<ul style="list-style-type: none"> “glucose” to be deleted 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “glucose” to be replaced with “sugar” 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “or “low blood sugar”).” to be included as part of explanation 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “or hypoglycaemia” to be deleted 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “your” to be included in “Do not leave <u>your</u> pen near heat or in direct light” 	n/a	n/a	Implemented	
	<ul style="list-style-type: none"> “pharmacist” to be included in statement “Your doctor, <u>pharmacist</u> or diabetic educator will show you to safely dispose of your needles and pre-filled pen once it is empty.” 	n/a	n/a	Implemented	N.B. “diabetic educator” was revised to “diabetes educator” prior to user testing.

CMI section(s) / subheading(s)	TGA proposed change(s) annotated on the CMI EDWG-developed CMI	Plavix® CMI Implemented / Not implemented	Ultibro® CMI Implemented / Not implemented	Toujeo® CMI Implemented / Not implemented	Rationale / comments
Full CMI: 6. Are there any side effects?	<ul style="list-style-type: none"> Most of the introductory paragraph in the section to be reworded to: “If you experience any, they will mostly be minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any questions about side effects.” 	Partially implemented	Partially implemented	Partially implemented	<p>Minor wording changes suggested to help the sentence be more conversational in nature.</p> <p>Partial implementation – recommended minor rewording to first amended sentence to: “If you do experience any side effects, most of them are minor and temporary”.</p>
	<ul style="list-style-type: none"> Lower case to be used for all bullet points (rather than sentence case) 	n/a (already included in original EDWG version)	Implemented	Implemented	
	<ul style="list-style-type: none"> Full stop to be included at the end of the last bullet point in the subsection 	n/a (already included in original EDWG version)	n/a (already included in original EDWG version)	Implemented	
	<ul style="list-style-type: none"> Statement on reporting side effects to be included: “You can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.” 	Implemented	Implemented	Implemented	
Full CMI: 7. Product details	<ul style="list-style-type: none"> A space to be included between the units and value for medicine strength 	Implemented	n/a	n/a	
	<ul style="list-style-type: none"> Full stop to be included at the end of the sentence 	Implemented	Implemented	Implemented	

Table 2. Summary of key changes made to each CMI that are relevant for CMI template development

CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
General / overall	<ul style="list-style-type: none"> Dark banding for all key headings throughout the document (both summary and full CMI) 	<p>✗</p> <p>(Banding of headings in the full CMI only, which was retained from original EDWG version for initial testing)</p> <p>N.B. The blue banding was changed to a darker blue to increase the contrast</p>	✓	✓	Similar design visual cues were intended to help orientate the user and to help ensure that people recognised that the summary CMI page is part of the complete document, comprising both the summary and full CMI. Consistent formatting of headings was then used after Week 1 testing.
	<ul style="list-style-type: none"> Single column format for summary page; two-column format for full CMI 	✓	✓	✓	This aspect was retained from the original EDWG version, with the two-column format being more user friendly based on the I-CMI study findings.
	<ul style="list-style-type: none"> Bolding of key statements / key subheadings / key actions to be taken 	✓	✓	✓	Each CMI was evaluated individually. Bolding was used to emphasise the key information, and was used consistently across the CMI where possible.
	<ul style="list-style-type: none"> Bullet points for lists of information 	✓	✓	✓	Original EDWG versions also used bullet points for lists of information.
	<ul style="list-style-type: none"> Use of subheadings with relevant information grouped underneath 	<p>✓</p> <p>(N.B. no additional subheadings proposed other than that included in the original EDWG version)</p>	✓	✓	Some additional subheadings were introduced for Ultibro® and Toujeo®, depending on the medicine. Some subheadings were adapted from the I-CMI study (e.g. things you should do). Some subheadings were also reworded.
	<ul style="list-style-type: none"> All subheadings were reformatted to be statements rather than questions, for consistency 	✓	✓	✓	The section heading itself is already formatted as a question. For consistency, all subheadings are formatted as statements.
	<ul style="list-style-type: none"> Less serious side effects presented before serious side effects 	✓	✓	✓	This aspect has been retained from the original EDWG version.

CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
	• General increased line spacing / white spacing where possible throughout the document	✓	✓	✓	Adequate white space improves readability of a document, as per good information design principles.
	• Reduction in use of all uppercase letters throughout the document e.g. use of sentence case for key headings instead of all uppercase	✓	✓	✓	All uppercase letters are harder to read than sentence case.
	• Removed use of contractions for consistency	✓	✓	✓	There was inconsistent use of contractions. For consistency, no contractions have been used throughout the CMI evaluated.
	• General attempt to simplify wording where appropriate (use of plain English)	✓	✓	✓	Use of plain English is critical to promote better understanding of written medicine information by users.
	• Reformatting to ensure that sentences were not unnecessarily split across two bullet points, where possible	✓	✓	✓	Orphan sentences should be avoided where possible, to aid with flow of information.
	• Sentences were started on a new line to improve clarity of key messages, where applicable	✓	✓	✓	
	• Consistent font used throughout the CMI	✓	✓	✓	Calibri font was retained from the original EDWG version for the text body. The footer font was also changed to ensure Calibri was consistently used.
Summary page	• Overall structure of the summary page, with subheadings mapped to the headings in the full CMI	✓	✓	✓	This aspect has been retained from the original EDWG version.
	• Links to “full CMI” for each section	✓	✗ (Links to the specific corresponding section in the full CMI were included, rather than just to the full CMI in general)	✗ (Links to the specific corresponding section in the full CMI were included, rather than just to the full CMI in general)	The changes to the Ultibro® and Toujeo® CMI improved navigation of the CMI documents.

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CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
	<ul style="list-style-type: none"> Reduced linking to the “full CMI” for every subsection, and linking to specific corresponding numbered section heading in full to help improve document navigation 	x	✓	✓	Not all information could be found in the summary and full CMI; mapping to subheadings may help to make the statements stand out per topic.
	<ul style="list-style-type: none"> 1.5 cm indent for summary page CMI information to reduce the white space on the right hand side 	✓	x (Not applicable due to the change in format of the summary page e.g. tabulation of Section 5 information)	x (Not applicable due to the change in format of the summary page e.g. tabulation of Section 5 information)	The indented information on the summary page for the Plavix® CMI was to improve readability.
	<ul style="list-style-type: none"> Numbering of headings on the summary page 	x (Original EDWG version retained for initial testing round)	✓	✓	This would ensure that the summary page is better mapped to the full CMI so it can be more effectively used as an index. This would help reduce the repetition of “see the full CMI” and reduce the chance of unsafe actioning of the information. It would also help participants recognise that similar information was presented under similar headings in both the summary and full CMI.
	<ul style="list-style-type: none"> Map key statements to the relevant key subheading under each section within the full CMI 	x (Minimal changes were made to the original EDWG version for the initial testing round)	✓	✓	It is important to ensure that all content included under each relevant subheading is also included in the same relevant section in the full CMI. Mapping to subheadings may help to make the statements stand out per topic.
	<ul style="list-style-type: none"> Inclusion of picture of medicine on the summary page 	x	x	✓	Inclusion of a picture of the medicine on the summary page was requested in the Week 2 testing.

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CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
Summary page subheading: 4. How do I take / use [medicine name]?	<ul style="list-style-type: none"> “More instructions” replacing “detailed instructions” / “for more information” 	✓	✓	✓	This change was completed to ensure that users did not misunderstand in thinking that all information could be found in the CMI e.g. device directions for use.
Summary page subheading: 5. What should I know while taking / using [medicine name]?	<ul style="list-style-type: none"> Tabulate information under the Section 5 subheading in the summary page, and ensure critical points of information are included within the table 	✗ (Minimal changes were made in the original EDWG version prior to initial testing round)	✓	✓	<p>Participants in Week 1 testing had some difficulty in locating the same information in both the summary and full CMI.</p> <p>Tabulation of the information under the Section 5 heading on the summary page was expected to help users more quickly understand what each distinct point referred to, in comparison to the previous format where several unrelated points were listed together.</p>
	<ul style="list-style-type: none"> Inclusion of information regarding storage in Section 5 of the summary 	✗	✗	✓	Storage is a critical point of information for Toujeo®.
Summary page subheading: 6. Are there any side effects?	<ul style="list-style-type: none"> Bullet points used for the list of side effects 	✓	✓	✗ (Only two side effects were mentioned on the summary page as per the original EDWG version. No further changes to content were made and subsequently, no bullet points were introduced)	As only two side effects were mentioned, bullet points were not used for the Toujeo® summary CMI.
	<ul style="list-style-type: none"> Ensure clinically relevant content is not inadvertently misunderstood between the summary and full CMI e.g. side effects and timely need for action to be taken for serious side effects 	✗ (Minimal content changes were made in the original EDWG version prior to initial testing round)	✓ (Deletion of reference to 1800 number and action to be taken from the summary page; users were referred to the full CMI for further information)	✓ (Minor wording change to reinforce that the action to be taken if side effects are experienced could be found in the full CMI)	There was a discrepancy between the actions to be taken included on the summary page when compared with the complete list of less serious and/or serious side effects included in the full CMI.

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CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
Beginning section of full CMI	<ul style="list-style-type: none"> “Consumer Medicine Information (CMI)” mentioned just below the full CMI title (medicine name), left justified rather than right justified 	✓	✓	✓	The two-column format is intended to be read from left to right. Therefore, if reading down the page, “Consumer Medicine Information (CMI)” should be left justified.
	<ul style="list-style-type: none"> CMI contents list written in sentence case rather than all uppercase letters 	✓	✓ (retained as already included in the original EDWG version)	✓	All uppercase letters are harder to read than sentence case.
Full CMI: 2. What should I know before taking [medicine name]?	<ul style="list-style-type: none"> Ensure pregnancy and breastfeeding information is only mentioned under the relevant subheading within Section 2 	✗	✗	✓ (This was already implemented as per the original EDWG version)	Participants commented on the degree of repetition in CMI. This was one point where repetition could be avoided.
Full CMI: 4. How do I take [medicine name]?	<ul style="list-style-type: none"> Blue highlighting of the external link to access further device instructions for use 	✗	✗	✓	Not all participants readily verbalised the external link included in the Ultibro® CMI. Use of highlighting was intended to help ensure that the link was not missed by users.
	<ul style="list-style-type: none"> Re-ordering of bullet points under “If you use too much Toujeo” to Poisons Information Centre, doctor, Emergency Department 	✗	✗	✓	This is a point of difference between the previous CMI and provided an opportunity to explore participants’ thoughts on the order.
Full CMI: 5. What should I know while I am taking [medicine name]?	<ul style="list-style-type: none"> Ensure the information regarding not to stop the medicine suddenly is located under the while you take section 	✗ (A direct statement about not stopping the medicine suddenly was not included in the full CMI as it was in the summary. Minimal content changes were made in the original EDWG version prior to initial testing round)	✓	✗ (“use Toujeo until your doctor tells you to stop” was included in Section 4. Hence, this information was also presented in Section 4 in the summary. This also allowed for a point of difference to see whether consistency of location in summary and full CMI was enough or whether people expected certain information to be in a particular section)	People expected to see this information under Section 5, as per the summary page in Week 1 testing. This was taken forward to Week 2 (Ultibro®) testing.

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CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
	<ul style="list-style-type: none"> Inclusion of subheading that could help ensure information about tests / monitoring effects of medicine is more obvious (e.g. things you should do) 	x	✓	✓	“Things you should do” has been introduced as per the heading used in the I-CMI study findings.
	<ul style="list-style-type: none"> Inclusion of subheading for information relating to disposal of the medicine 	x	✓	✓	Information is currently under “Looking after your medicine”; does not particularly fit under this heading.
	<ul style="list-style-type: none"> Separating out information about alcohol use and driving / using machines 	x	✓	✓	This was intended to help improve the clarity of the information, as per the I-CMI study findings.
	<ul style="list-style-type: none"> Inclusion of subheading relating to when to discard the medicine 	x	x	✓	Discard-by date of 28 days relevant to Toujeo®. An appropriate subheading was therefore introduced for this key information.
Full CMI: 6. Are there any side effects?	<ul style="list-style-type: none"> Minor rewording of side effects introductory paragraph 	✓	✓	✓	To simplify and clarify the information presented.
	<ul style="list-style-type: none"> Side effects were presented in a table 	✓	✓	✓	Tabulated side effects was liked and worked well when user tested in the I-CMI study.
	<ul style="list-style-type: none"> Grouping of side effects under subheadings according to their effect on the body to help manage long lists of side effects 	✓	✓	✓	Side effect grouping was intended to make lists of side effects more manageable for CMI users.
	<ul style="list-style-type: none"> Separate tables introduced for each subgroup of serious side effects due to the length of the serious side effects list 	✓	x (Serious side effects could be conveyed in the same table without significant formatting issues)	x (Serious side effects could be conveyed in the same table without significant formatting issues)	Separate tables would mean that the action to be taken could be repeated and clearly conveyed side by side in the Plavix® CMI.
	<ul style="list-style-type: none"> Subheading for reporting side effects introduced 	✓	✓	✓	This is new information in the CMI and distinct from clinical content. A subheading would help consistently convey this information as part of a CMI template.

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CMI section(s) / subheading(s)	Document aspect (Design / content / wording)	Week 1 testing Plavix® CMI	Week 2 testing Ultibro® CMI	Week 3 testing Toujeo® CMI	Rationale / comments
	<ul style="list-style-type: none"> Subheadings introduced for the level of severity of the side effects (before each relevant table) 	x	✓	✓	This was introduced to supplement the table column heading to make the severity of the side effects stand out for users.
Full CMI: 7. Product details	<ul style="list-style-type: none"> Active and inactive ingredients presented in a table 	✓	✓	✓	This was intended to better support CMI users to quickly identify / check the active and inactive ingredients.
	<ul style="list-style-type: none"> Further explanation for medicine ingredients by using alternative expressions side by side: express inactive ingredient as other ingredients, and active ingredient as main ingredient 	x	✓	✓	The term inactive was queried in Week 1 testing. Therefore, to help improve people's ability to understand his information, the wording from the current CMI was also used to help explain what inactive ingredients refer to.
	<ul style="list-style-type: none"> Inclusion of the statement "Do not use this medicine if you are allergic to any of these ingredients." directly under the tabulated ingredients 	✓ (Minor rewording of the statement included in the original EDWG version)	✓	x (This statement was not included in the original EDWG version)	The point of difference between the CMI provided an opportunity to see whether such a statement is needed (in addition to the mention of allergy and ingredients in Section 2).
	<ul style="list-style-type: none"> Inclusion of a picture of the medicine, included alongside the description in Section 7 	x (Minimal content changes were made in the original EDWG version prior to initial testing round)	✓	✓	Inclusion of a picture was suggested by participants to complement the written description. This was also raised in the I-CMI study.

3.3 User testing methods

In order to determine the usability of these CMI formats, User Testing was conducted. This method was developed by Sless and colleagues,⁴ and is widely implemented in the European Union⁷ to evaluate the usability of medicine information leaflets and ensure that required performance benchmark standards are met.

The protocol for the conduct of this study mirrored that extensively used by our research team in other user testing projects spanning over-the-counter (non-prescription) medicine labels,⁸⁻¹⁰ dispensed prescription medicine labels¹¹ and CMI leaflets.² Consequently, there are similarities in the content and style of reporting of these user testing studies that are acknowledged for this report.

The user testing process constituted evaluating the usability of the CMI via the administration of a validated user testing questionnaire, and evaluating a consumer's⁷:

- ability to find information, and
- ability to understand the medicine information.

3.4 User testing questionnaire development

The CMI were appraised and key medicine information were identified by The University of Sydney research team to help inform the development of the user testing questionnaire. Broad key medicine information points were kept consistent as best as possible between the CMI to ensure that the overall findings could be compared between the cohorts. Specific questions were derived from the I-CMI study² and/or previous user testing research conducted within the team⁸ to allow for comparison between the present study and previous research. Questions were centred on facts, explanations, and actions required, as per the I-CMI study.²

Several key points of information could be found in both the summary and full CMI, as detailed in Table 3. Up to 15 questions were asked in each user testing questionnaire per study medicine CMI (Table 4), and indicative answers to the user testing questionnaire were designated *a priori* once each CMI was finalised for testing.

Table 3. Key medicine information in the user testing questionnaire and their location in the summary and/or full CMI

Key medicine information	Location of information in the CMI					
	Plavix®		Ultibro®		Toujeo®	
	Summary CMI	Full CMI	Summary CMI	Full CMI	Summary CMI	Full CMI
Indication for the medicine	✓	✓	✓	✓	✓	✓
Dosage of the medicine	✓	✓	✓	✓	✓	✓
Allergy – lactose	✗	✓	✗	✓	✗	✓
Disposal of medicine	✗	✓	✗	✓	✓	✓
Less serious side effects	✗	✓	✗	✓	✗	✓
Less serious side effects – action to be taken	✗	✓	✗	✓	✗	✓
Important or serious side effects and action(s) to be taken	✗	✓	✗	✓	✗	✓
Contraindication(s) / precaution(s) and action to be taken	✗	✓	✗	✓	✗	✓
Drug-drug interaction	✗	✓	✗	✓	✗	✓
Missed dose and action to be taken	✗	✓	✗	✓	✗	✓
Stopping the medicine	✓	✓	✓	✓	✓	✓
Use during pregnancy	✓	✓	✓	✓	✓	✓
Tests / monitoring before and/or during treatment with the medicine	✗	✓	✓	✓	✓	✓
Driving and using the medicine	✓	✓	✓	✓	n/a	n/a
Explanation – why doctor should be notified of upcoming surgery	✗	✓	n/a	n/a	n/a	n/a
Explanation – why doctor should be notified of frequent hypoglycaemia	n/a	n/a	n/a	n/a	✓	✓
Storage	n/q	n/q	n/q	n/q	✓	✓

n/a = not applicable to the respective CMI.

n/q = no user testing questionnaire item on storage asked.

The questions were ordered to ensure that questions where answers could be found in both the summary and full CMI were not asked consecutively. Similarly, the order of questions ensured that the answers to two questions in a row were not derived from the same section in the CMI.

Table 4. User testing questionnaire overview for all study CMI

Key medicine information	Plavix®	Ultibro®	Toujeo®
Indication for the medicine	What is Plavix® used for?	What is Ultibro® used for?	What is Toujeo® used for?
Dosage of the medicine	What is the normal dose of this medicine?	What is the normal dose of this medicine?	What is the normal dose of this medicine?
Use of the device (N.B. responses to this question were analysed separately)	n/a	Describe to me how you would take / use this medicine?	Describe to me how you would take / use this medicine?
Use during pregnancy	Imagine you are planning to become pregnant. Is there anything you should know about this medicine and its use during pregnancy?	Imagine you are planning to become pregnant. Is there anything you should know about this medicine and its use during pregnancy?	Imagine you are planning to become pregnant. Is there anything you should know about this medicine and its use during pregnancy?
Drug-drug interaction	Imagine you are currently taking Plavix® and your doctor prescribes you a new medicine called ibuprofen. What does the leaflet say about how it can interact with Plavix®?	Imagine you are currently using Ultibro® and your doctor prescribes you a new medicine called prednisolone. What does the leaflet say about how it can interact with Ultibro®?	Imagine you are currently using Toujeo® and your doctor prescribes you a new medicine called prednisolone. What does the leaflet say about how it can interact with Toujeo®?
Existing allergy / allergy to ingredient	Imagine you have an allergy to one of the ingredients in this medicine called 'Lactose'. What does the leaflet say about using this medicine?	Imagine you have an allergy to one of the ingredients in this medicine called 'Lactose'. What does the leaflet say about using this medicine?	Imagine you have an allergy to 'Lactose'. What does the leaflet say about using this medicine?
Missed dose and action to be taken	Imagine that you usually take your medicine at 8 o'clock in the evening. You realise at 3 o'clock in the afternoon that you have forgotten to take your medicine the night before. What does the leaflet say you should do?	Imagine that you usually use your medicine at 8 o'clock in the evening. You realise at 3 o'clock in the afternoon that you have forgotten to use your medicine the night before. What does the leaflet say you should do?	Imagine that you usually use your medicine at 8 o'clock in the evening. You realise at 3 o'clock in the afternoon that you have forgotten to use your medicine the night before. What does the leaflet say you should do?
Stopping the medicine	Imagine you are taking Plavix®. Are you able to quickly stop taking Plavix® on your own?	Imagine you are using Ultibro®. Are you able to quickly stop using Ultibro® on your own?	Imagine you are using Toujeo®. Are you able to quickly stop using Toujeo® on your own?

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Key medicine information	Plavix®	Ultibro®	Toujeo®
Less serious side effects	What are three less serious side effects that you have to watch out for?	What are three less serious side effects that you have to watch out for?	What are three less serious side effects that you have to watch out for?
Less serious side effects – action to be taken	What does the CMI tell you to do if these side effects occur?	What does the CMI tell you to do if these side effects occur?	What does the CMI tell you to do if these side effects occur?
Disposal of medicine	Your doctor tells you that you do not need to take Plavix® anymore. What does the leaflet say you should do with the tablets you still have?	Your doctor tells you that you do not need to use Ultibro® anymore. What does the leaflet say you should do with the capsules you still have?	If you started using your Toujeo® pen 2 weeks ago, what is its use-by date?
Important or serious side effects and action(s) to be taken	You have been taking Plavix® for the past few days. This morning, you felt ill and vomited. You noticed that your vomit was blood-coloured, and contained small brown lumps. What should you do?	You have been using Ultibro® for the past few days. This morning, you noticed that your eyesight was not normal, and you were seeing halos. What should you do?	You have been using Toujeo® for the past few days. This morning, you felt ill. You noticed that your heart was beating very fast, you were extremely hungry, and your eyesight was affected. What should you do?
Tests / monitoring before and/or during treatment with the medicine	Why might you need to do some tests when taking Plavix®?	What should you do if you find that Ultibro® is not helping with your symptoms as much as it normally would?	When using Toujeo®, what should you keep an eye on regularly?
Contraindication(s) / precaution(s) and action to be taken	Imagine you are taking Plavix®. You just remembered that you have surgery booked in with your dentist next week. What does the leaflet say you should do?	If you have heart problems, what should you do before starting to use Ultibro®?	If you are training hard right now for a marathon run next month, what should you do before starting to use Toujeo®?
Driving and using the medicine	Imagine you are a truck driver. Are you able to take this medicine and still continue with your work? Can you explain your answer?	Imagine you are a truck driver. Are you able to use this medicine and still continue with your work? Can you explain your answer?	n/a
Explanation of the importance of contacting the doctor in a given scenario	Why should you tell your doctor about the surgery you have booked in with the dentist next week?	n/a	Why is it important for you to tell your doctor if you keep on having low blood sugar levels?
Storage	n/a	n/a	Imagine you have just brought home some new Toujeo® pens from your local pharmacy. Where should they be stored if you have not used them yet?

3.5 User testing interviews

This study was approved by The University of Sydney Human Research Ethics Committee (project number 2019/122). All user testing interviews took place in May 2019 in one of the rooms in the premises of The City Group Rooms (<https://cgr.com.au/>), in either Sydney CBD, Parramatta or Hurstville. All interviews were conducted by the same research team member (VT) for reliability and validity.

3.5.1 Sample size

As per user testing protocol, 10 people were needed per user testing cohort to evaluate each CMI document. Therefore, a total of 30 participants were needed for the study.

3.5.2 Recruitment and inclusion / exclusion criteria

Participants were recruited by the market research company Chitchat Research (<http://www.chitchatresearch.com.au/>) according to set inclusion / exclusion criteria detailed below, adapted from previous research.^{2, 8, 9, 11}

Inclusion criteria:

- 18 years or older
- Has sufficient English skills to read and understand the consent form, participant information sheet and CMI, and participate in the user testing session without the need for assistance from an interpreter
- Has not used the assigned study medicine (clopidogrel or insulin or indacaterol / glycopyrronium) or a medicine that is from the same therapeutic class (anti-platelet medicines; anti-diabetic; or medicines for treatment of chronic obstructive pulmonary disease; respectively) either currently or within the last 6 months prior to study participation.

Exclusion criteria:

- A health care professional (HCP) (whether practising or retired) or who is currently employed in an occupation which primarily deals with medicine information
- Is significantly visually impaired
- Is significantly cognitively impaired
- Has participated in a user testing study within the last 6 months.

Age, sex and education were the three main demographic factors which underpinned the sampling recruitment criteria (as per previous research).

In order to ensure that each cohort was demographically matched, the following sampling criteria guided recruitment per cohort of 10 participants that evaluated each respective CMI document:

- **Age:** at least one person in each decade between 30 and 70+ years
- **Sex:** Minimum of three participants per sex
- **Education:** No more than three higher education graduates (based on data published by the Australian Bureau of Statistics¹²)
- **Written information use:** at least two participants who either did not use written documents as part of their work, or who were currently not working or retired.

3.5.3 User testing interview process

All interviews were audio-recorded with written consent from the participants.

Interviews took approximately 60 minutes and were structured as follows:

- a) Initial welcome and information provided about the study
- b) Administration of the user testing questionnaire and recording of participants' responses to the questions
- c) Semi-structured interview component collating qualitative feedback on the CMI format(s)
- d) Additional demographic data collected and conclusion of the interview session.

Remuneration was provided for consumer participation in the study (\$80 per participant).

3.6 Data analysis

All audio recordings of the interviews were reviewed together with the annotated responses and notes / observations made by the interviewer during the user testing interview sessions. Each UTQ item response was reviewed and coded against the indicative answer in relation to the two key outcome measures (ability to find information and ability to understand the located information).

In addition to this, the number of participants who could find and understand the key medicine information was then compared to the success criteria detailed in best practice guidance published by the UK Medicine and Healthcare products Regulatory Agency (MHRA),¹³ which states:

*"Success criteria were published in "Always Read the Leaflet". These state that **90% of literate adults should be able to find the information and of these 90% should be able to understand the information.** Over two rounds of 10 participants on the final proposed leaflet we **would expect 16/20 participants to have both found and understood the information.**"¹³*

Taking into consideration the study design and that there was only one round of user testing per CMI for this study, a simplified interpretation of this guidance was applied. Key medicine information was considered as well communicated, and the standard having been met, if at least 8/10 in the cohort were able to find and understand the relevant medicine information, rather than 90% of 90%.

For questions where the key medicine information could be found in both the summary and full CMI, the information was coded as found **if** the relevant information could be sourced by the participant in **both** the summary and full CMI. This meant that if the information was only found in either the summary or full CMI, this was coded as not found.

Responses for questions where the key medicine information was included in **both** the summary and full CMI were analysed to determine whether:

- the information was able to be found in **both** the summary and full CMI (coded as found),
- the information was first found in the summary or full CMI (first location found),
- if the information was only found in **either** the summary or full CMI (therefore not in both), then where the information was found.

The qualitative component of the user testing session was content analysed, with specific emphasis on identifying key issues contributing to poor usability, and subsequent improvements that could be made. Participant perspectives on the CMI evaluated in comparison to the existing / current CMI available, and the summary page together with the full CMI were also collated for reporting.

4. Results

4.1 Participant demographics

Overall, a total of 31 people were recruited to user test one of the three study CMI (Table 5). Recruitment targets for each cohort were designated according to the demographic matching criteria provided *a priori* to the market research company by the research team.

It should be noted that an additional participant was intentionally recruited for the Plavix® cohort to address an identified recruitment oversight i.e. the higher than desired proportion of university graduates in the Plavix® cohort.

Table 5. Demographics summary

Demographic		Plavix® cohort (n=11)	Ultibro® cohort (n=10)	Toujeo® cohort (n=10)	Total (n=31)
Gender	Male	5	5	5	15
	Female	6	5	5	16
Age (years)	18-29	2	1	1	4
	30-39	3	1	1	5
	40-49	2	3	3	8
	50-59	2	2	2	6
	60-69	1	2	2	5
	70+	1	1	1	3
Highest level of education attained	School certificate (Year 10) or below	0	1	0	1
	Higher School Certificate (Year 12)	0	1	1	2
	TAFE / College qualification	7	5	6	18
	Bachelor's degree or higher	4	3	3	10
Regular use of written information as part of occupation	Yes	9	6	8	23
	No	2	4	2	8
Main language(s) spoken at home	English	10	9	10	29
	Other	1	2	1	4

4.2 User testing findings

4.2.1 CMI reading times

Average reading times for the CMI were determined within each user testing cohort (Table 6). The Toujeo® CMI had the longest average reading time of the three study CMI.

Table 6. CMI reading times

CMI (n)	Mean reading time (minutes)	Median reading time (minutes)	Minimum reading time (minutes)	Maximum reading time (minutes)
Plavix® (n=11)	04:30	04:05	01:44	07:42
Ultibro® (n=10)	04:45	04:46	02:13	07:25
Toujeo® (n=10)	05:41	04:43	02:51	09:18

4.2.2 User testing questionnaire – quantitative findings

The following section outlines the main quantitative findings from the study, including:

- A summary of the user testing questionnaire findings (Table 7), reporting how many participants were able to find the key medicine information, and how many participants were able to understand or interpret the information;
- An overview of how the summary and full CMI were used by participants when locating key medicine information (Table 8). This table reports the number of participants who were able to find the key medicine information in **both** the summary and full CMI (where the information was included in both the summary and full CMI), and where they found the information **first** (summary or full CMI). This table also reports the number of participants who could only find the information in one place (summary or full CMI), and where they found this information; and
- Integrated high-level explanations of the key quantitative findings.

Table 7. Summary of user testing questionnaire quantitative findings (excluding information regarding device use)

Key medicine information	Plavix® (n=11)		Ultibro® (n=10)		Toujeo® (n=10)	
	Found (n)	Understood (n)	Found (n)	Understood (n)	Found (n)	Understood (n)
Indication for the medicine	9	9	10	10	10	10
Dosage of the medicine	11	11	10	10	8	8
Existing allergy / allergy to ingredient	10	10	8	8	4	4
Disposal of medicine	11	11	10	10	10	10
Less serious side effects	11	11	10	10	10	10
Less serious side effects – action to be taken	11	11	10	10	10	10
Important or serious side effects and action(s) to be taken	11	11	10	10	2	2
Contraindication(s) / precaution(s) and action to be taken	Upcoming surgery	8	8	*	*	*
	Cardiovascular conditions	*	*	10	10	*
	Excessive exercise	*	*	*	*	10
Drug-drug interaction	11	11	9	9	9	9
Missed dose and action to be taken	11	11	10	10	10	10
Stopping the medicine	7	7	10	10	7	7
Use during pregnancy	8	8	10	10	10	10
Tests / monitoring before and/or during treatment with the medicine	6	6	10	10	10	10
Driving and using the medicine	8	8	10	10	*	*
Explanation – why doctor should be notified of upcoming surgery	10	10	*	*	*	*
Explanation – why doctor should be notified of frequent hypoglycaemia	*	*	*	*	4	4
Storage	*	*	*	*	10	10

* Question not applicable to the medicine or no user testing questionnaire item was asked.

Table 8. Findings detailing whether information was first located by the consumer in the summary or full CMI (excluding information regarding device use)

Key medicine information included in <u>both</u> the summary and full CMI	Plavix® (n=11)				Ultibro® (n=10)				Toujeo® (n=10)			
	Total number of consumers who found information in <u>both</u> summary and full CMI, and where they found the information first		Total number of consumers who found information in <u>either</u> summary or full CMI, and where they found the information		Total number of consumers who found information in <u>both</u> summary and full CMI, and where they found the information first		Total number of consumers who found information in <u>either</u> summary or full CMI, and where they found the information		Total number of consumers who found information in <u>both</u> summary and full CMI, and where they found the information first		Total number of consumers who found information in <u>either</u> summary or full CMI, and where they found the information	
	Summary first (n)	Full CMI first (n)	Summary (n)	Full CMI (n)	Summary first (n)	Full CMI first (n)	Summary (n)	Full CMI (n)	Summary first (n)	Full CMI first (n)	Summary (n)	Full CMI (n)
Indication for the medicine	6	3	1	1	8	2	0	0	9	1	0	0
Dosage of the medicine	2	9	0	0	6	4	0	0	0	8	0	2
Stopping the medicine	2	5	1	2	5	5	0	0	4	3	1	0
Use during pregnancy	5	3	0	3	6	4	0	0	3	7	0	0
Tests / monitoring before and/or during treatment with the medicine	*	*	*	*	5	5	0	0	4	6	0	0
Driving and using the medicine	2	6	0	3	7	3	0	0	*	*	*	*
Explanation – why doctor should be notified of frequent hypoglycaemia	*	*	*	*	*	*	*	*	2	2	0	5
Storage	*	*	*	*	*	*	*	*	6	4	0	0
Disposal of medicine	*	*	*	*	*	*	*	*	4	6	0	0

* Question not applicable to the medicine or the information was not included in both the summary and full CMI.

Integrated high-level explanations of the key quantitative findings

The following tables and explanatory notes provide a comparison of all three CMI documents evaluated in this study and the key high-level user testing findings.

Key / Legend

Cells highlighted in green ✓	No major changes to the relevant section of the CMI are needed, because <ul style="list-style-type: none"> At least 8 people within the cohort of 10 (or 9/11 for the Plavix® cohort) could find and understand the key information This meant that the industry standard was met and the CMI worked well for this information
Cells highlighted in amber !	Some change(s) to the relevant section of the CMI are needed, because <ul style="list-style-type: none"> Between 5 and 7 people within the cohort (8 for the Plavix® cohort) could find and understand the key information; and/or Participant feedback about, and their use of, the document indicated confusion or suboptimal document usability
Cells highlighted in red ✗	Changes to the relevant section of the CMI are needed, because <ul style="list-style-type: none"> Less than 5 people within the cohort could find and understand the key information

Key medicine information clearly communicated across [all](#) study CMI

Key medicine information	Plavix®	Ultibro®	Toujeo®
Indication for the medicine	✓	✓	✓
Disposal of medicine	✓	✓	✓
Less serious side effects	✓	✓	✓
Less serious side effects – action to be taken	✓	✓	✓
Drug-drug interaction	✓	✓	✓
Missed dose and action to be taken	✓	✓	✓

How participants used the summary and full CMI

Indication for the medicine

- Indication information could be found in both the summary and full CMI by almost all participants.
- Of those who could find the information in both, the majority found the information in the summary CMI first.

Reason(s) why the information was effectively communicated in the study CMI

Clear headings

- “1. Why am I taking / using [medicine name]?” – indication for the medicine.
- “3. What if I am taking other medicines?” – drug-drug interaction.

Clear subheadings

- “If you forget to take / use [medicine name]” – what to do if a dose has been missed.
- “Looking after your medicine” – information on storage and disposal included together in the Plavix® CMI.
- “Getting rid of any unwanted medicine” – first introduced in the Ultibro® CMI.
- “When to discard your medicine” – introduced in the Toujeo® CMI for medicine-specific details.

Tabulation of side effects

- Tabulating side effects and action(s) to be taken, based on severity.

Clearer explanations

- How the medicine can interact with Toujeo® was written in bold before the relevant medicines were listed; the information was more specific in this CMI compared to the Plavix® and Ultibro® CMI.

Key medicine information clearly communicated in [specific study](#) CMI

Key medicine information	Plavix®	Ultibro®	Toujeo®
Explanation – why doctor should be notified of upcoming surgery	✓	n/a	n/a
Storage	n/a	n/a	✓

How participants used the summary and full CMI

Storage

- Approximately equal numbers of consumers found this information in the summary or full Toujeo® CMI first.

Reason(s) why the information was effectively communicated in the study CMI

Location of information – linking actions to explanations

- Explanations relating to communication with the doctor required for upcoming surgery were included near the action in the Plavix® CMI. Due to its importance, relevant information was included in more than one CMI section.

Plain English and logical ordering of information

- Storage information under the “Looking after your medicine” heading in the Toujeo® CMI was consolidated and simplified using plain English, with clear statements presented in step-wise, chronological order (how to store before use, just prior to first use, and after first use).

Similar information included in the table in the summary CMI

- Key storage information was also tabulated in the summary Toujeo® CMI in the same chronological order as the full CMI.

Key medicine information better communicated [as a result of changes](#) made from the findings of the Plavix® CMI user testing

Key medicine information	Plavix®	Ultibro®	Toujeo®
Stopping the medicine	!	✓	!
Use during pregnancy	!	✓	✓
Tests / monitoring before and/or during treatment with the medicine	!	✓	✓
Driving and using the medicine	!	✓	n/a

Comparing usability across the CMI

- The ability of participants to locate the relevant information in both the summary and full CMI improved as a result of changes made to the CMI after the Plavix® CMI user testing.
- Although information advising to use the medicine until the doctor tells you to stop was included in the same Toujeo® CMI section (Section 4) in the summary and full CMI, it was not as direct (as Ultibro®) and not included in Section 5 where at least one participant was expecting to find the information.

How participants used the summary and full CMI

Stopping the medicine

- Participants successfully found information about not stopping the medicine suddenly in both the summary and full Ultibro® CMI.
- Not all who user tested the Plavix® CMI could find the relevant information in both the summary and full CMI. The statement “do not stop taking Plavix suddenly” included in the summary CMI was not explicitly stated in the same way in the full CMI, and was not included in the same corresponding section in the full CMI.

Use during pregnancy

- Unlike for the Ultibro® and Toujeo® CMI, not all participants could locate the pregnancy-related information in both the summary and full Plavix® CMI.

Tests / monitoring before and/or during treatment with the medicine

- Approximately equal proportions found the information in the summary or full CMI first for action to be taken / information relevant to monitoring for Ultibro® and Toujeo®.

Driving and using the medicine

- A higher proportion found the warning about driving in the summary CMI first for Ultibro®, compared to Plavix®. This information was included in the table in the summary CMI that was first introduced in the Ultibro® CMI.

Reason(s) why the information was effectively communicated in the study CMI

Clear subheadings

- Information about not stopping the medicine suddenly was included under the subheading “Things you should not do” in the Ultibro® CMI.
- Information relating to monitoring required while taking the medicine was included under the subheading “Things you should do” – introduced in the Ultibro® and Toujeo® CMI.

Tabulated key points in the summary CMI under “5. What should I know while using [medicine name]?”

- The subheading “Things you should not do” included in the table in the summary CMI corresponded to the full Ultibro® CMI.

Clear, consistent statement included under the same heading in both the summary and full CMI

- Concise and direct statement about not stopping the medicine suddenly was included in Section 5 in both the summary and full CMI for Ultibro® CMI, which was not the case for the Plavix® CMI.

Consistent formatting between the summary and full CMI

- This has led to improved ability to find the pregnancy-related information in the Ultibro® and Toujeo® CMI, compared to Plavix®.
- Numbered headings that were consistent in both the summary and full CMI supported better document navigation and subsequently, supported finding similar information in both the summary and full CMI.

Links / cross-referencing included in summary CMI to individual sections in the full CMI

- This was a general improvement that supported better document navigation from the summary to the full CMI.

Identified issues and key considerations [for tailoring the CMI template](#) to a specific medicine and dosage form

Key medicine information	Plavix®	Ultibro®	Toujeo®
Dosage of the medicine	✓	!	!

Comparing usability across the CMI

- The dosage for Plavix® was well found and understood by participants.
- Although participants who user tested a CMI for a non-oral dosage form (Ultibro® and Toujeo®) could find and understand the relevant information for dosage, aspects about the dosage were unclear for several participants, for example:
 - Whether one puff of Ultibro® equated to one capsule (put into the device and the contents inhaled), and
 - Whether the Toujeo® pre-filled pen was single-use or multi-use.
- It was not explicitly stated whether one capsule was the equivalent to one puff for Ultibro®. This information is included in the current CMI but not included in the EDWG-supplied and user tested CMI. There was also a lack of directions for use of the device included in the full CMI.
- There was no specific dose of Toujeo® stated in the CMI; people were looking for a specific number / amount.

How participants used the summary and full CMI

- Dosage was most commonly found in the full CMI first for Plavix® and Toujeo®, rather than in the summary CMI.

Key medicine information	Plavix®	Ultibro®	Toujeo®
Existing allergy / allergy to ingredient	✓	!	✗

Comparing usability across the CMI

Ultibro® CMI

- Although the minimum number required were able to find and understand this information, there was a degree of difficulty seen within the cohort for this question. Active ingredients were not explained in Section 1 before the relevant action to be taken, if allergic, in Section 2 (as per the Plavix® full CMI). Together with the complicated / lengthy active ingredient names themselves, this meant that the second half of the bullet point was more likely to be missed. This is a content-specific issue rather than a format-specific issue.

Toujeo® CMI

- Toujeo® did not contain lactose, which was the allergy described in the given scenario. To answer the question, it was expected that participants were able to locate the ingredients under Section 7, and conclude that they would be able to use the medicine as it did not contain lactose.
- Many had difficulty with this question for Toujeo®.

Reason(s) why the information was effectively communicated in the study CMI

Clear statement introducing the active ingredient(s) relating them to the medicine's indication in Section 1

- The first sentence under the Section 1 heading in the Plavix® full CMI was "Plavix contains a medicine called clopidogrel". Therefore, when reading "Do not take Plavix if: you are allergic to clopidogrel or any ingredients listed at the end of this leaflet", the information was communicated well.

Simplified, tabulated medicine ingredients under the subheading "What [medicine name] contains" in Section 7

- Only the Plavix® active and inactive ingredients themselves were listed in the table.
- Ingredients were not complicated by stating the amount per capsule and the specific salt forms included (as seen in the Ultibro® CMI).

Key medicine information	Plavix®	Ultibro®	Toujeo®
Contraindication(s) / precaution(s) and action to be taken	!	✓	✓

Comparing usability across the CMI

- Information about what to do if you are already taking Plavix® and have upcoming surgery was located in Section 5 of the full CMI. People tended to find and focus on the warning information included under Section “2. What should I know before I take Plavix?” instead.
- The precautions information required for the scenarios relating to Ultibro® and Toujeo® were clearly stated in Section 2.

Reason(s) why the information was effectively communicated in the study CMI

Bolding for emphasis – action to be taken

- “Check with your doctor if you:” bolded under Section 2 before the precautions are listed.

Use of bullet points to list information

- The relevant precautions were listed using bullet points under the bolded action to be taken.

Key medicine information	Plavix®	Ultibro®	Toujeo®
Important or serious side effects and action(s) to be taken	✓	✓	✗

Comparing usability across the CMI

- Participants that evaluated the Plavix® or Ultibro® CMI were able to find and understand the action to be taken for the serious side effects presented in the scenario.
- For the Toujeo® CMI, the symptoms in the scenario could be mapped to early symptoms of mild to moderate hypoglycaemia. Mild to moderate hypoglycaemia is indicative of both suboptimal management of diabetes, and in this case, also a less serious side effect. Relevant information was therefore included in both Sections 5 and 6 on what to do if it is experienced.
- Participants required prompting to locate the relevant information under Section 5 of the heading. People generally expected this type of information to be found under Section 6 ("6. Are there any side effects?"). Once this information was found however, participants struggled to make the connection that they should also consider speaking to their doctor about this less serious side effect of mild to moderate hypoglycaemia. There were also other actions to be taken listed in Section 5 that may have confounded this e.g. make sure people close to you know how to recognise the symptoms of low blood sugar.

Reason(s) why the information was effectively communicated in the study CMI

Tabulation of side effects

- In the Plavix® and Ultibro® CMI, the tabulated side effects based on severity, and grouped based on effect on the body within each table, effectively enabled participants to identify the correct action to be taken for the given scenario.

All relevant information included under one heading in the CMI

- All information required to respond to the side effects scenario using the Plavix® and Ultibro® CMI could be found under Section "6. Are there any side effects?".

Key medicine information	Plavix®	Ultibro®	Toujeo®
Explanation – why doctor should be notified of frequent hypoglycaemia	n/a	n/a	*

How participants used the summary and full CMI

- Half of the cohort only found this information in the full CMI.

Reason(s) why the information was not effectively communicated in the study CMI

Information not located in the section of the summary CMI that corresponded to participant expectation and CMI document use

- Participants generally located the information in Section 5 of the full CMI (“5. What should I know while using Toujeo?”). The explanation was included after the bolded instruction to notify the doctor of frequent hypoglycaemia. However, in the summary CMI, the explanation was not included in the table.
- Although a similar explanation was also included in Section 4 of the full CMI (“4. How do I use Toujeo?”) and in the corresponding heading in the summary CMI, based on participant CMI use, this information would have been better communicated in Section 5 of the summary CMI instead.

4.2.3 High-level qualitative findings

The following table outlines the high-level qualitative findings from the semi-structured component of the user testing session. Where verbatim quotes have been used, the participant number for the CMI evaluated has been reported.

Table 9. Summary of high-level qualitative findings by topic of discussion

Topic of discussion	High-level findings
General impressions	<p>Common perspectives across all three CMI</p> <p>a) Positives</p> <ul style="list-style-type: none"> The majority of participants liked all three study summary and full CMI Participants felt that the three study CMI were inviting and the information was well presented There was a “good logical approach” (Ultibro® #5) to all three CMI <p>b) Negatives</p> <ul style="list-style-type: none"> Some believed that there was “too much duplication of information” (Ultibro® #1) <p>Ultibro® CMI</p> <ul style="list-style-type: none"> Links in the document signalled that this document was designed to be used in an online / electronic format (Ultibro®)
Likes	<p>Common perspectives across all three CMI</p> <p>Participants liked:</p> <ul style="list-style-type: none"> the bolding to highlight important information the headings being in question format clear headings the numbering of the headings, as it allowed for cross-referencing and navigation through the document side effects grouped and tabulated – made the information easier to digest <p>Plavix® CMI</p> <p>Participant(s) liked:</p> <ul style="list-style-type: none"> having less serious side effects first then the serious side effects (Plavix®) <p>Repetition in CMI</p> <ul style="list-style-type: none"> Opinions were mixed regarding the degree of pregnancy information repetition within the CMI (Plavix®) <p>External link with more information</p> <ul style="list-style-type: none"> Opinions on including an external link for more information regarding instructions for device use were mixed; whilst several queried the usefulness of a link for those who are not as computer literate / elderly, others who may have accessed information online more regularly were comfortable with it (Ultibro®)

Topic of discussion	High-level findings
Dislikes	Repetition in CMI <ul style="list-style-type: none"> Participants disliked the repetitiveness; “people are smart enough, put the information in the one place” (Plavix® #7) “Tiny bit repetitive, but you need that to reinforce information” (Plavix® #1)
Appearance / design	Common perspectives across all three CMI <ul style="list-style-type: none"> Overall, participants liked aspects that followed good information writing and design, such as bulleted lists, clear headings, and numbered headings Design of headings <ul style="list-style-type: none"> Participants liked the use of colour in the headings (Plavix®) Participants liked the black banded headings; one participant did comment that the black was a bit “heavy” though and when asked, would have preferred navy blue (Ultibro®)
Ability to find information	Common perspectives across the CMI <p>a) Positives</p> <ul style="list-style-type: none"> Overall, the majority of participants for all three CMI commented that navigating the CMI was easy Information was in general in a logical place, and participants found it easy to understand (Plavix®, Ultibro®) <p>b) Negatives</p> <ul style="list-style-type: none"> However, there were some sections that were harder to navigate such as side effects (Toujeo®)
Content – Language	Common perspectives across all three CMI <ul style="list-style-type: none"> In general, the three CMI did not have difficult language The language “does not alienate” the reader or anyone from a “non-English speaking background” (Ultibro® #7) Difficulty in understanding <ul style="list-style-type: none"> <u>Medicine class</u>: The medicine class names were difficult for people as people did not know the name of medicine classes. A recommendation was to provide examples of the medicines in the class (Plavix®). <u>Active and inactive ingredients</u>: One participant commented that people do not understand what “active” and “inactive” ingredients mean. “It’s a bit like washing powder... what are active ingredients?” (Plavix® #4) Unhelpful information <ul style="list-style-type: none"> “Talk to your doctor” was reported as an unhelpful statement, as there is no indication of urgency; and for people who do not have a regular doctor, this statement can be regarded as meaningless (Plavix®)

Topic of discussion	High-level findings
Content – Amount of information	<p>Positives</p> <ul style="list-style-type: none"> • Very informative document (Plavix®) <p>Negatives</p> <ul style="list-style-type: none"> • Participants felt there was a lot of information; some were overwhelmed – on occasion, people could remember they had read a particular point somewhere but had significant difficulty finding it again or could not find it (Toujeo®) • The information about tests is irrelevant for a patient because the doctor will inform patients what tests they need to have done and patients have trust in their doctor (Plavix®) <p>Mixed opinions</p> <ul style="list-style-type: none"> • There were mixed opinions about the level of detail required for directions for use for a device in a CMI and whether a video was enough (Toujeo®)
Summary CMI page	<p>Common perspectives across all three CMI</p> <ul style="list-style-type: none"> • In general, people liked the concept of a summary page and found it useful; however, for the most part, people said that it would not be enough to be given on its own as a one-page document <p>Plavix® summary CMI</p> <ul style="list-style-type: none"> • The summary page can appear as repetitive as the same information is also found in the full CMI, but as the medicine is an important medicine, it is essential to have the summary page and have the important information repeated (Plavix® #4) • The summary page acted as a reference for the full CMI content; therefore if the information does not match between the two, it presents as a problem for finding information in the full CMI (Plavix® #5) <p>Ultibro® summary CMI</p> <ul style="list-style-type: none"> • A few participants did state that having the summary page alone would be sufficient as there were links to the full CMI that could be used as needed • The summary page alone would also work for people as the only CMI document, if the links were such that the person can get onto an online version of the full CMI <p>Toujeo® summary CMI</p> <ul style="list-style-type: none"> • In general, there were mixed opinions on the summary page for the Toujeo® e.g. it was liked as a summary to refer to; could just be replaced with the table of contents; it was suggested to get rid of it in general as the full CMI contained the information
Suggested Improvements	<p>Design / formatting</p> <ul style="list-style-type: none"> • Would like to see picture of the medicine • Ensure important information that are in a paragraph, are bulleted so that they stand out (Plavix®) • Colour coding of less severe and more severe side effects, so that it is easier for people to distinguish between the two (Plavix®)

Topic of discussion	High-level findings
	<p>Language / wording used</p> <ul style="list-style-type: none"> • Important to be clear about what people “should do” and what they “should not do” whilst on the medicine (Plavix® #7) • A recommendation was to be more direct in the language used to communicate certain important information, such as “Do Not Drink” when communicating advice on avoiding alcohol with the medicine (Plavix® #2) • The section “before taking this medicine, tell your doctor” should be reworded to say “have you told your doctor”, as a way of checking with the doctor (Plavix® #4) <p>Content / amount of information</p> <ul style="list-style-type: none"> • More detailed information about the drug interactions and what will happen (Plavix®) • More details about the changes that would occur when on a medicine e.g. what is “normal bleeding” or “normal bruising” when on Plavix®, and what would be “abnormal” (Plavix® #10) • Provide further information where there is “Tell / talk to your doctor” (Plavix®) • Elaboration needed on what would happen if a dose is missed (Ultibro®) • Add information regarding how long the person should be on the medicine (Ultibro®) • Be more specific about the information and explain what is meant, for example what does “too much exercise” mean? (Toujeo® #6) • Put in a statement that states “if your allergy is not listed, you are fine” (Toujeo® #7)
<p>Comparison with existing CMI</p>	<p>Preference between the existing / current CMI versus the revised CMI tested</p> <ul style="list-style-type: none"> • <u>Plavix®</u>: The majority preferred the revised Plavix® CMI format (the user tested format) over the current Plavix® CMI format; the current CMI format was perceived to be overwhelming to read, a lot of information, and not as user-friendly; one participant however did prefer the current CMI format and preferred side effects to all be listed, rather than divided into tables • <u>Ultibro®</u>: The majority preferred the revised Ultibro® CMI format (the user tested format) over the current Ultibro® CMI format; both rounds to date have led to largely consistent critique of the current CMI, with similar issues raised • <u>Toujeo®</u>: More participants within the cohort in this round preferred the existing CMI format over the tested CMI format, compared with the previous user testing rounds. The three-column format made it seem like the information was easier to go through. However, overall the revised Toujeo® CMI format was still generally preferred <p>Aspects where the revised CMI format was better</p> <ul style="list-style-type: none"> • Having two columns was reported as making the document much easier to read than the three-column format, which made the document look dense

Topic of discussion	High-level findings
	<p>Aspects where the existing / current CMI was better</p> <ul style="list-style-type: none"> • The list of side effects in the current Plavix® CMI appeared less than the side effects information tabulated in the revised Plavix® CMI • “Looking after your medicine” section in the existing CMI is better than the tested CMI because of the layout, headings and information content (Plavix®) • The wording of “Do not be alarmed” about the list of side effects was preferred, as it feels “kinder” (Plavix® #2) <p>Criticisms about the existing / current CMI</p> <ul style="list-style-type: none"> • Too much information in the existing Plavix® CMI, which can give “anxieties to me”; “doesn’t invite me to read it” (Plavix® #3) • The current CMI is like the “Encyclopaedia Britannica” (Ultibro® #1) • There is a lot of “superfluous information” in the existing Ultibro® CMI (Ultibro® #8) <p>Mixed opinions – level of content</p> <ul style="list-style-type: none"> • On the whole, there were mixed opinions about the level of detail / content needed; interestingly, people would like more information in some instances, when they were shown the existing CMI and felt they were missing out on key information when comparing with the revised CMI that was tested (Toujeo®)
Other comments	<ul style="list-style-type: none"> • Do not want to see the CMI in tiny print, folded up and placed inside the box, as would just throw it put (Plavix® #1) • The CMI should be designed in such a way that a person can easily access and find the information when “they are panicking” (Toujeo® #2)

4.3 The CMI template

A final revised CMI template (Figure 1) was produced by The University of Sydney research team based on, and underpinned by the:

- user testing findings from this study, primarily The University of Sydney quantitative findings,
- evidence-based findings from the current CMI research in the literature,
- existing national and international guidelines to support written medicine information development, and
- feedback received on the three study CMI and the draft template presented at the stakeholder workshop.

Unique features of the CMI template

✓ Summary CMI with key points mapped to the full CMI (page 1 of the template)

- Tabulating key points under the heading “5. What should I know while using [medicine name]?”
- Links / cross-referencing to individual sections in the full CMI to improve document navigation from the summary CMI
- Consistent formatting between the summary and full CMI
- Presenting key points under the same headings / subheadings within the summary and full CMI for consistency

✓ Revised grouping and tabulation of side effects (page 4 of the template)

- Inserting separate tables for side effects based on the side effect severity and the recommended action(s) to be taken
- Subgrouping of side effects within each table according to their effect on the body
- Clear subheadings to highlight the side effect severity and any further subgrouping within each table

✓ Tabulation of the medicine ingredients (page 4 of the template)

- Tabulating active and inactive ingredients
- Medicine ingredients moved higher up in the section “7. Product details”, before information about what the medicine looks like

✓ A subheading called “Warnings” under the heading “2. What should I know before I use [medicine name]?” (page 2 of the template)

[medicine name]*

Consumer Medicine Information (CMI) summary
Important information about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI). The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using [medicine name]?
[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to
For more information, see Section 3, [What you should know before using \[medicine name\]](#), in the full CMI.

2. What should I know before I use [medicine name]?
Do not use it if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.
Tell your doctor if you:

- have any other medical conditions
- take any medicines for any other medical conditions
- are pregnant or plan to become pregnant or are breastfeeding

For more information, see Section 2, [What you should know before using \[medicine name\]](#), in the full CMI.

3. What if I am taking other medicines?
Some medicines may interfere with [medicine name] and affect how it works.
A list of these medicines is in Section 2, [What if you are taking other medicines?](#), in the full CMI.

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement regarding device use / other important directions for use]

More instructions can be found in Section 4, [How do I use \[medicine name\]](#), in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	Things you should not do
<ul style="list-style-type: none"> • Read and follow any doctor or dentist you visit that you are using [insert medicine] • Insert other relevant key points (e.g. monitoring of the condition / effectiveness of medicine) 	<ul style="list-style-type: none"> • Do not stop using the medicine suddenly (if relevant) • Insert other relevant key points
<p>Other relevant subheadings(s)</p> <ul style="list-style-type: none"> • [Insert this table to any condition-specific or medicine-specific subheadings(s) as per the full CMI] • Insert other relevant key points 	
<p>Driving or using machines</p> <ul style="list-style-type: none"> • Insert relevant information regarding any warnings to consider before driving or operating machinery • Insert other relevant key points 	
<p>Drinking alcohol</p> <ul style="list-style-type: none"> • Insert relevant statement regarding drinking alcohol while using the medicine • Insert other relevant key points 	
<p>Storing after your medicine</p> <ul style="list-style-type: none"> • Insert storage details, in particular any formulation-specific storage details (e.g. refrigerate do not freeze) • Insert other relevant key points 	

For more information, see Section 5, [What you should know while using \[medicine name\]](#), in the full CMI.

6. Are there any side effects?
[Describe statement of potential side effects, and any less side effects in particular that need to be noted]
For more information on these side effects and what to do if you have any side effects, see Section 6, [Are there any side effects?](#) in the full CMI.

[medicine name]*

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]</p> <ul style="list-style-type: none"> • [Insert as appropriate] <p>[Grouping 2 as per effect on body]</p> <ul style="list-style-type: none"> • [Insert as appropriate] 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Insert appropriate action</p>

Serious side effects

Serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]</p> <ul style="list-style-type: none"> • [Insert as appropriate] <p>[Grouping 2 as per effect on body]</p> <ul style="list-style-type: none"> • [Insert as appropriate] 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.
Other side effects not listed here may occur in some people.

Reporting side effects
After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](#). By reporting side effects, you can help provide more information on the safety of this medicine.
Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

[medicine name]*

7. Product details
This medicine is only available with a doctor's prescription.

What [medicine name] contains

Active ingredient	Insert
Other ingredients (inactive ingredients)	Insert

Do not take this medicine if you are allergic to any of these ingredients.

What [medicine name] looks like
[medicine name] is... [Insert R.XXXXXXX]

Who distributes [medicine name]
[Insert sponsor name and contact details]

This leaflet was prepared in [insert month and year].

Evidence-based elements that continue to support optimal document design and usability:

✓ Good information design

- Bolding of key actions to be taken and key messages, for emphasis
- Increasing white space between lines to help make the information easier to read
- High contrast headings throughout the document (white font on dark coloured background / band)
- Numbering headings to support document navigation
- Using appropriate subheadings within the key headings to help group and emphasise information

[medicine name]* (phonetic pronunciation – optional)
Active ingredient(s) (medicine active ingredient(s)) (phonetic pronunciation – optional)

Consumer Medicine Information (CMI)

This leaflet provides important information about using [medicine name]. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].

Where to find information in this leaflet:

1. [What you should know before using \[medicine name\]](#)
2. [What you should know while using \[medicine name\]](#)
3. [What you should know after using \[medicine name\]](#)
4. [What you should know about other medicines](#)
5. [What you should know about other medicines](#)
6. [What you should know about other medicines](#)

1. Why am I using [medicine name]?
 [medicine name] contains the active ingredient [insert active ingredient]. [medicine name] is [insert therapeutic class and indication].
 [medicine name] is used to [insert indication].

2. What should I know before I use [medicine name]?

Warnings:

Do not use [medicine name] if:

- you are allergic to [active ingredient], or any of the ingredients listed at the end of this leaflet.
- (Always check the ingredients to make sure you can use this medicine.)
- [insert other relevant contraindications].

Check with your doctor if you:

- have any other medical conditions (list any notable ones for the medicine/ medical condition level)
- take any medicines for any other condition
- [insert specific precautions relevant to the medical condition]

During treatment, you may face the risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6, [What you should know about other medicines](#).

3. What should I know while using [medicine name]?

Things you should do:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Things you should not do:

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant actions]

4. How do I use [medicine name]?

How much to take / use [medicine name]

- [include relevant dosage information]
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

When to take / use [medicine name]

[medicine name] should be used [insert as relevant].

How to [insert appropriate verb] [medicine name] [relevant for devices]

- [insert relevant steps by user instructions / considerations for device use]

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also link to the relevant external links from internal document section links.

If you forget to use [medicine name]

[medicine name] should be used regularly at the same time each day (week or month). If you miss your dose at the usual time, [insert appropriate explanation].

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

➔ Include explanation of what "missed time for your next dose" refers to for the specific medicine where possible (e.g. oral contraceptives).

➔ Include any other medicine specific action and advice re missed dose, as appropriate.

If you use too much [medicine name]

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre on 0800 135 070, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should be alert if there are no signs of discomfort or poisoning.

5. What should I know while using [medicine name]?

Things you should do:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Things you should not do:

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant actions]

6. What you should know about other medicines

Relevant condition-specific or medicine-specific subheading(s)

- This refers to any medical condition-specific, medicine-specific, and/or use-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

7. What you should know about other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you are taking without a prescription from your pharmacy, supermarket or health food shop.

8. What you should know about other medicines

[Include an explanation of the nature of the interaction, depending on the nature of their interactions – an example of this is included below, or]

- [tabulating these medicines that have been grouped according to the nature of their interactions, or]
- If there is only one list of medicines, then ensuring that the information is presented consistently.

Some medicines may interfere with [medicine name] and affect how it works.

[Include an explanation of the nature of the interaction where possible] e.g.

Medicines that may increase the effect of [medicine name] include:

- [list medicines as appropriate]

Medicines that may reduce the effect of [medicine name] include:

- [list medicines as appropriate]

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].

[medicine name]* 2

✓ Appropriate content and wording

- Using plain English throughout the document
- Defining all medical / scientific terms
- Using clear statements
- Using consistent wording when conveying similar information
- Reducing unnecessary repetition throughout the document

4. How do I use [medicine name]?

How much to take / use [medicine name]

- [include relevant dosage information]
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

When to take / use [medicine name]

[medicine name] should be used [insert as relevant].

How to [insert appropriate verb] [medicine name] [relevant for devices]

- [insert relevant steps by user instructions / considerations for device use]

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also link to the relevant external links from internal document section links.

If you forget to use [medicine name]

[medicine name] should be used regularly at the same time each day (week or month). If you miss your dose at the usual time, [insert appropriate explanation].

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

➔ Include explanation of what "missed time for your next dose" refers to for the specific medicine where possible (e.g. oral contraceptives).

➔ Include any other medicine specific action and advice re missed dose, as appropriate.

If you use too much [medicine name]

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre on 0800 135 070, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should be alert if there are no signs of discomfort or poisoning.

5. What should I know while using [medicine name]?

Things you should do:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant actions to be taken]
- [include relevant statements re action to be taken if the condition worsens / does not improve]

Things you should not do:

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant actions]

6. What you should know about other medicines

Relevant condition-specific or medicine-specific subheading(s)

- This refers to any medical condition-specific, medicine-specific, and/or use-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

7. What you should know about other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you are taking without a prescription from your pharmacy, supermarket or health food shop.

8. What you should know about other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you are taking without a prescription from your pharmacy, supermarket or health food shop.

9. What you should know about other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you are taking without a prescription from your pharmacy, supermarket or health food shop.

10. What you should know about other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you are taking without a prescription from your pharmacy, supermarket or health food shop.

[medicine name]* 3

Figure 1. The CMI template

[medicine name]*

Consumer Medicine Information (CMI) summary

Important information about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI).

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to

For more information, see Section [1. Why am I using \[medicine name\]?](#) in the full CMI.

2. What should I know before I use [medicine name]?

Do not use it if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you:

- have any other medical conditions
- take any medicines for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use \[medicine name\]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor or dentist you visit that you are using [insert medicine]. • [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly (if relevant). • [Insert other relevant key point(s)]
[Other relevant subheading(s)]	<ul style="list-style-type: none"> • [Note: this refers to any condition-specific or medicine-specific subheading(s) as per the full CMI] • [Insert other relevant key point(s)]
Driving or using machines	<ul style="list-style-type: none"> • Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	<ul style="list-style-type: none"> • Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	<ul style="list-style-type: none"> • Insert storage details, in particular any formulation-specific storage details e.g. refrigerate do not freeze • [Insert other relevant key point(s)]

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information on these side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

[medicine name]*

1

[medicine name]* (phonetic pronunciation – optional)

Active ingredient(s): [medicine active ingredient(s)] (phonetic pronunciation – optional)

Consumer Medicine Information (CMI)

This leaflet provides important information about using [medicine name]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].**

Where to find information in this leaflet:

1. [Why am I using \[medicine name\]?](#)
2. [What should I know before I use \[medicine name\]?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use \[medicine name\]?](#)
5. [What should I know while using \[medicine name\]?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using [medicine name]?

[medicine name] contains the active ingredient [insert active ingredient]. [medicine name] is [insert therapeutic class and explanation].

[medicine name] is used to [insert indication].

2. What should I know before I use [medicine name]?

Warnings

Do not use [medicine name] if:

- you are allergic to [active ingredient], or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- [insert other relevant contraindications].

Check with your doctor if you:

- have any other medical conditions [list any notable ones for the medicine / medical condition here]
- take any medicines for any other condition
- [insert specific precautions relevant to the medical condition].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

[Include any other relevant pregnancy information specific to the medicine].

[Relevant condition-specific or medicine-specific subheading(s)]

- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

[Options here include either:

- subdividing and listing the medicines depending on the nature of their interaction – an example of this is included below, or;

- tabulating these medicines that have been grouped according to the nature of their interaction, or;

- if there is only one list of medicines, then ensuring that the information is presented consistently.]

Some medicines may interfere with [medicine name] and affect how it works.

[Include an explanation of the nature of the interaction where possible] e.g.

Medicines that may increase the effect of [medicine name] include:

- [list medicines as appropriate]

Medicines that may reduce the effect of [medicine name] include:

- [list medicines as appropriate]

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].

4. How do I use [medicine name]?

How much to take / use

- [include relevant dosage information]
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

When to take / use [medicine name]

- [medicine name] should be used [insert as relevant].

How to [insert appropriate verb] [medicine name] (relevant for devices)

- [insert relevant step-by-step instructions / considerations for device use]

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also help to distinguish external links from internal document section links.

If you forget to use [medicine name]

[medicine name] should be used regularly at the same time each day [week or month]. If you miss your dose at the usual time, [insert appropriate explanation].

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- ➔ [include explanation of what “almost time for your next dose” refers to for the specific medicine where possible e.g. oral contraceptives]
- ➔ [include any other medicine-specific action and advice re missed dose, as appropriate]

If you use too much [medicine name]

If you think that you have used too much [medicine name], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using [medicine name]?

Things you should do

[Include relevant action(s) and explanation(s)]

Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant action(s) to be taken]
- [include relevant statement(s) re action to be taken if the condition worsens / does not improve]

Remind any doctor or dentist you visit that you are using [medicine name].

Things you should not do

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant actions(s)]

[Relevant condition-specific or medicine-specific subheading(s)]

- Some medicines may require additional subheading(s) relevant to monitoring the condition and actions to be taken while on the medicine e.g. bleeding risk with antiplatelets / hypoglycaemia and what to do.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how [medicine name] affects you.

[medicine name] may cause dizziness in some people (or insert relevant information, as appropriate).

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may [insert effect relevant to use of the medicine].

Looking after your medicine

- [include device-specific storage information]
- [include storage information] e.g.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

[Include any specific information re discarding the medicine e.g. 28 day expiry from date of first use].

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]:</p> <ul style="list-style-type: none"> • [list as appropriate] <p>[Grouping 2 as per effect on body]:</p> <ul style="list-style-type: none"> • [list as appropriate] 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>[Insert appropriate action]</p>

Serious side effects

Serious side effects	What to do
<p>[Grouping 1 as per effect on body e.g. bleeding-related]:</p> <ul style="list-style-type: none"> • [list as appropriate] <p>[Grouping 2 as per effect on body]:</p> <ul style="list-style-type: none"> • [list as appropriate] 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

[medicine name]*

7. Product details

This medicine is only available with a doctor's prescription.

What [medicine name] contains

Active ingredient (main ingredient)	[insert]
Other ingredients (inactive ingredients)	[insert]

Do not take this medicine if you are allergic to any of these ingredients.

What [medicine name] looks like

[medicine name] is... (Aust R XXXXXX).

Who distributes [medicine name]

[insert sponsor name and contact details]

This leaflet was prepared in [insert month and year].

5. Conclusions, recommendations and future directions

5.1 Conclusions

The iterative process of CMI development, consumer user testing, CMI modification, and further consumer user testing has led to the development of a CMI template that is effective at communicating the key medicine information tested. This CMI template can act as a guide for development of future, and revision of existing, CMI for prescription and non-prescription (over-the-counter) medicines.

Furthermore, a summary page which serves as the first page of the CMI template, providing pertinent medicine information needed for safe and effective use of the medicine, and directing the user to more detailed information in the full CMI, was developed and user tested. This summary page worked best as a document linked to the full CMI, which consumers used to glean pertinent information and identify relevant sections in the full CMI for more information.

5.2 Recommendations

The following recommendations are made based on the findings of this study:

CMI development

- Use Good Information Design and Writing Principles in guiding CMI development; and ensure that existing national and international guidelines become part of the practice of CMI development. Specifically:
 - Reduce repetition
 - Place content where it makes sense
 - Use pictures of medicine or medicine container / packaging, where appropriate.
- Use the consumer user testing process conducted as part of this study to user test all future redesigned and rewritten CMI, as well as novel digital CMI formats, even if the CMI template and relevant guidelines have been used in the CMI development process.

Summary CMI page and full CMI

- Ensure each medicine has a summary and full CMI.
- Ensure consistency between the summary and full CMI, with cross-referencing and linking of the same sections.
- Achieve consensus on the wording of non-clinical content and content that is not medicine-specific, to be used consistently throughout all CMI documents.
- Achieve consensus for the clinical content selected for inclusion in the summary CMI from the full CMI. Depending on how the document is used, summarising information may lead to less clarity if people choose to only refer to the summary CMI.

CMI template use for CMI development

- Ensure that critical information is not left out of any précised CMI when tailoring the CMI template to specific medicines such as devices. A shorter CMI does not necessarily mean it is a clearer CMI, particularly if critical clinical content is inadvertently omitted.
- Achieve consensus on the level of clinical content to be transferred from current CMI to CMI developed using the CMI template.
- Confirm the CMI subheadings most appropriate to use across different medicines / dosage forms / medicine classes.

Instructions for use

- Achieve consensus on the level of detail of instructions for device use to be included in the full CMI. If there is a package insert and/or link to a video / additional resource, this should be mentioned consistently.

Active and inactive ingredients

- Achieve consensus on how active ingredients and inactive ingredients are expressed within the table i.e. whether the medicine strength is conveyed alongside the active ingredient (e.g. per unit dose) or whether they are just stated.

Contraindication(s) / precaution(s) and action to be taken

- Consider the use of specific subheadings where there are distinct precautions that need to be taken.
- Ensure that the information is better placed in sections where people are expecting to find the specific information. User testing will help CMI writers better understand patterns of CMI use by consumers.
- Another option may be to reinforce specific information in both Section 2 (“What should I know before I use [medicine name]?”) and Section 5 (“What should I know while using [medicine name]?”) if it is a critical issue / action to be taken.

Important or serious side effects and action(s) to be taken

- Achieve consensus on how to convey information that relates to side effects, worsening or poor management of the medical condition, overdose, and similar side effects with varying severity (e.g. mild to moderate hypoglycaemia was a less serious side effect of Toujeo® whereas severe hypoglycaemia was considered a serious side effect).
- Where possible, include all relevant information under the same heading.

CMI template implementation

- Develop a CMI template for digital versions of CMI.
- Establish a governance structure that includes all key stakeholders (led by the TGA or authorised group / individual who reports to the TGA) which can oversee the implementation of the CMI template.
- Establish a process for the implementation and review of CMI changes including the revised CMI template, and consumer user testing of redeveloped CMI.
- Review the CMI legislation to ensure relevance to contemporary and future consumer information needs.

5.3 Future directions – policy, practice and research

- Mandate the use of the CMI template and consumer user testing of CMI.
- Set up a quality assurance process by which the CMI template can be further user tested and refined, following user testing protocol.
- Consumer user testing of each developed CMI to evaluate clinical content navigation, understanding and interpretation by consumers.
- Development of medicine class specific Core CMI to aid clinical content wording development and ensure consistency across medicine classes.
- Increase consumer awareness of CMI.
- Increase health care professional awareness of revised CMI template.

5.4 Study limitations

One of the important limitations of this study is that only one cohort of 10 consumers user tested each summary and full CMI document. User testing is an iterative diagnostic process whereby a document is user tested with 10 consumers, its weaknesses identified, changes made to improve the document, and the document user tested again with a new cohort of 10 participants. This iterative process is repeated until within a minimum of two cohorts of 10 consumers, 90% have found the key medicine information, and of these, 90% have demonstrated their understanding of the information.^{7, 13} To reduce this limitation, a total of three cohorts of 10 consumers were involved in the user testing and iterative improvement of the CMI documents for the ultimate development of the CMI template in this study.

Due to the study inclusion criteria, there were no participants from a culturally and linguistically diverse background who had difficulty with reading English and/or conversing in English. Therefore, the CMI were not tested in these subpopulations.

The CMI template has been based on user testing data for three dosage forms and as such, it should be acknowledged that the CMI template may not cover inclusion of information that is specific to a particular medicine or dosage form or delivery system.

6. References

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Appendices

Appendix 1	EDWG-supplied Plavix® CMI
Appendix 2	EDWG-supplied Ultibro® CMI
Appendix 3	EDWG-supplied Toujeo® CMI
Appendix 4	Final user tested Plavix® CMI
Appendix 5	Final user tested Ultibro® CMI
Appendix 6	Final user tested Toujeo® CMI

Appendix 1. EDWG-supplied Plavix® CMI

PLAVIX (PLAV-IX)**Important facts you need to know about your medicine**

This page contains the most important points from the Consumer Medicine Information (CMI). The CMI has more details and can be found in the [full CMI](#) over the page. If you are worried about using this medicine, ask your doctor or pharmacist.

Why am I taking Plavix ?

Plavix is used to prevent blood clots forming in hardened blood vessels that may lead to stroke, a heart attack or even death. For more information, see [full CMI](#).

What should I know before I take Plavix ?

Don't use it if you have had an allergic reaction to Plavix before. Talk to your Doctor if:

- A) You have any other medical conditions
- B) You take any medicines for any other condition
- C) you are pregnant or plan to become pregnant or are breast-feeding.

For more information, see [full CMI](#).

What if I'm taking other medicines ?

Some medicines may interfere with Plavix and affect how it works. For more information, see [full CMI](#).

How do I take Plavix ?

The usual dose of Plavix is one 75mg tablet daily, with or without food. For more information, see [full CMI](#).

What should I know while taking Plavix?

Remind any Doctor or Dentist when you visit that you are using Plavix. Tell your Doctor immediately if you become pregnant. Do not stop taking Plavix suddenly. Be careful driving or operating machinery until you know how Plavix affects you. When drinking alcohol, dizziness may be worse.

For more information, see [full CMI](#).

Are there any Side Effects ?

Serious side effects include dizziness, unusually heavy bleeding, bloody or black bowel motions, nausea or vomiting, red or purple spots visible through your skin, itching, inflamed or cracked or red skin. If you have any concerns about using this medicine, speak with your Doctor or Pharmacist or call 1800 123 456.

For more information, please see [full CMI below](#).

PLAVIX* Tablets

CONSUMER MEDICINE INFORMATION (CMI)

This leaflet provides important information about taking Plavix. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or queries about taking Plavix.**

Where to find information in this leaflet:

1. [WHY AM I TAKING PLAVIX ?](#)
2. [WHAT SHOULD I KNOW BEFORE I TAKE PLAVIX ?](#)
3. [WHAT IF I'M TAKING OTHER MEDICINES ?](#)
4. [HOW DO I TAKE PLAVIX ?](#)
5. [WHAT SHOULD I KNOW WHILE I'M TAKING PLAVIX ?](#)
6. [ARE THERE ANY SIDE EFFECTS ?](#)
7. [PRODUCT DETAILS](#)

1. WHY AM I TAKING PLAVIX?

Plavix contains a medicine called clopidogrel. It belongs to a group of medicines called anti-platelet medicines that prevent the clumping of small blood cells (platelets) together during clotting.

Plavix works by preventing blood clots forming in hardened blood vessels that may lead to stroke, heart attack or death.

You may have been prescribed Plavix because:

- you have previously suffered a heart attack, stroke or have peripheral arterial disease
- you have suffered Acute Coronary Syndrome.

2. WHAT SHOULD I KNOW BEFORE I TAKE PLAVIX?

Do not take Plavix if:

- you are allergic to clopidogrel or any ingredients listed at the end of this leaflet
- you have a medical condition causing bleeding
- you suffer from severe liver disease

Check with your doctor if:

- you have had recent surgery (including dental surgery) or are planning to have surgery in the next two weeks.
- you are allergic to other antiplatelet medicines (e.g. ticlopidine, prasugrel)
- if you are pregnant or are planning to have a baby. See additional information under [Pregnancy and breastfeeding](#)
- If you have or have had any medical conditions, especially the following:

- bleeding disorders or blood clotting problems
- any illness or disability caused by bleeding
- recent serious injury
- any form of liver disease.

During treatment, you may be at risk of developing certain side effects. **It is important you understand these risks and how to monitor for them.** See additional information under [side effects](#).

Pregnancy and Breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. If you become pregnant while taking Plavix, speak with your doctor as soon as possible to discuss the possible risks and benefits of continuing to take Plavix.

Talk to your doctor if you are breastfeeding or intend to breastfeed as the doctor may need to change your medicine.

3. WHAT IF I'M TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins, supplements or remedies. **Some medicines may interfere with Plavix and affect how it works. These include:**

- anticoagulant and anti-platelet medicines such as aspirin, heparin and warfarin. Note: your doctor may prescribe aspirin with Plavix if you have Acute Coronary Syndrome
- non-steroidal anti-inflammatory drugs
- medicines for stomach ulcers or reflux disease
- medicines for gastric reflux (e.g. omeprazole).
- phenytoin for epilepsy
- tolbutamide for diabetes
- tamoxifen for breast cancer
- fluvastatin to lower cholesterol
- some antidepressant medicines

Check with your doctor or pharmacist if you are not sure about what medicines you are taking and if these medicines may affect Plavix.

4. HOW DO I TAKE PLAVIX?

How much to take

- The usual dose of Plavix is one 75 mg tablet daily with or without food.

- Swallow with a glass of water or other liquid.
- If you are prescribed Plavix for the treatment of Acute Coronary Syndrome, you may receive a starting dose of 300 mg, then one 75 mg tablet daily.

Take Plavix as prescribed by your doctor and until your doctor tells you to stop. Do not give this medicine to anyone else.

If you forget to take Plavix

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. **Do not take a double dose to make up for the dose you missed.**

If you take too much (overdose)

If you think that you or anyone else may have taken too much Plavix, you may need urgent medical attention.

You should immediately:

- telephone the Poisons Information Centre (ph: 13 11 26) or
- go to the Emergency Department at your nearest hospital or
- contact your doctor

5. WHAT SHOULD I KNOW WHILE I'M TAKING PLAVIX?

Bleeding and Plavix

Sometimes bleeding may occur in your body while you are taking Plavix or it may take longer to stop bleeding. **To manage your risk you should:**

- tell all doctors, dentists, nurses and pharmacists treating you that you are taking Plavix (e.g. surgery or dental work)
- ask your doctor about any activities to avoid (e.g. sport)
- have any blood tests your doctor orders

Call your doctor straight away if you have:

- an injury or are injured
- abnormal bruising or bleeding
- abnormal nose bleeds
- bloody or black bowel motions
- red or purple blotches on your skin

If you are taking both aspirin and Plavix your risk of bleeding may be increased.

Alcohol, driving and using machinery

Plavix may cause faintness or dizziness in some people. **Be careful driving or operating machinery until you know how Plavix affects you.**

If you drink alcohol, faintness or dizziness may be worse.

Looking after your medicine

- Do not start a new packet if the packaging is torn or shows signs of being opened
- Do not take the tablets after the expiry date on the pack has passed.
- Keep tablets in the blister pack until it is time to take them.
- Store your Plavix in a cool, dry place where the temperature stays below 25°C.
- **Keep your tablets where young children cannot reach them.**
- If you no longer need to take Plavix or the expiry date, has passed, take the Plavix tablets to any pharmacy for safe disposal.

6. ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you experience them, most are minor and temporary, however some may need medical attention. Ask your doctor or pharmacist to answer any questions you may have about side effects.

Speak to your doctor if you have any of the following less serious side effects and they worry you:

- diarrhoea
- itching
- pain or stiffness in the joints
- things taste different.

Call your doctor straight away if you notice any of the following serious side effects:

- bloody or black bowel motions
- diarrhoea with blood, mucous, stomach pain and fever
- nausea or vomiting, or vomiting of blood or vomit that looks like coffee grounds
- abdominal or stomach pain
- coughing up blood
- blood in the eyes or in your urine
- unusually heavy bleeding from cuts or wounds
- bleeding (including nose bleeds) or bruising more easily than normal
- unusually heavy or unexpected menstrual bleeding
- numbness or problems with co-ordination
- nausea or vomiting
- faintness, dizziness, light-headedness or blurred vision
- slurred speech or other difficulty in speaking
- headache (severe and continuing), confusion or hallucinations
- fever or other signs of infection
- rash or hives
- chills, sweating or clammy skin, fever, muscle weakness or pain, loss of appetite and fatigue
- weight loss
- anaemia (tired and pale looking)
- red or purple spots visible through your skin

- itching, inflamed, cracking or red skin
- chest tightness, wheezing, coughing or difficulty breathing
- yellowing of the skin or whites of the eyes, pale stools and dark urine with vomiting and stomach pain
- swelling of the face, lips, mouth, tongue or throat causing difficulty in swallowing or breathing.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. PRODUCT DETAILS

What does Plavix look like ?

- Plavix 75mg tablets are pink round tablets with '75' engraved on one side and '1171' on the other. A box contains 28 tablets. (AUST R 78622)
- Plavix 300mg tablets are pink oblong tablets with '300' engraved on one side and '1332' on the other. A box contains 30 tablets. (AUST R 151257)

What does Plavix contain?

Active ingredient: clopidogrel.

Inactive ingredients: mannitol, macrogol 6000, microcrystalline cellulose, hydrogenated castor oil, hydroxypropylcellulose, hypromellose, lactose, titanium dioxide, glycerol triacetate, red iron oxide, carnauba wax

Do not take this medicine if you are allergic to any of the above ingredients.

Who distributes Plavix?

Sanofi–Aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park
NSW 2113

Tel: 1800 818 806

This leaflet was prepared in February 2019

Appendix 2. EDWG-supplied Ultibro® CMI

ULTIBRO BREEZHALER 110/50

IMPORTANT FACTS YOU NEED TO KNOW ABOUT YOUR MEDICINE

This page contains the most important points from the Consumer Medicine Information (CMI). The CMI has more details and can be found in the [full CMI](#) over the page. If you are worried about using this medicine, ask your doctor or pharmacist.

Why am I using Ultibro Breezhaler 110/50 ?

Ultibro Breezhaler is used for treating chronic obstructive pulmonary disease, also called COPD.

For more information, see [full CMI](#).

What should I know before I use Ultibro Breezhaler 110/50 ?

Don't use it if you have had an allergic reaction to Ultibro Breezhaler 110/50 before.

Talk to your doctor if:

- You have any other medical conditions
- you take medicines for any other medical condition
- you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see [full CMI](#).

What if I'm taking other medicines ?

Some medicines may affect how Ultibro Breezhaler 110/50 works.

A list of these medicines is in the [full CMI](#).

How do I use Ultibro Breezhaler 110/50 ?

You need to have one puff of Ultibro Breezhaler 110/50, once every day.

Detailed instructions can be found [here](#).

What should I know while using Ultibro Breezhaler 110/50?

- Remind any doctor or dentist when you visit that you are using Ultibro Breezhaler 110/50.
- Tell your doctor immediately if you become pregnant.
- Do not stop using Ultibro Breezhaler 110/50 suddenly.
- Be careful driving or operating machinery until you know how Ultibro Breezhaler 110/50 affects you.
- When drinking alcohol, dizziness may be worse.

For more information, see [full CMI](#).

Are there any side effects ?

The most serious side effects that some people have had are:

Feeling breathless, chest feeling tight, wheezing, cough, pain or uncomfortable feeling in the eyes.

If there is anything that worries you about this medicine, speak with your doctor or pharmacist or call 1800 123 456.

For more information, please see [full CMI below](#).

ULTIBRO BREEZHALER 110/50* TABLETS

CONSUMER MEDICINE INFORMATION (CMI)

This leaflet has important information about taking Ultibro Breezhaler 110/50. **Speak to your doctor or pharmacist if you want more information or if you have any concerns about taking Ultibro Breezhaler 110/50.**

Where to find information in this leaflet:

1. [Why am I using Ultibro Breezhaler 110/50?](#)
2. [What should I know before I use Ultibro Breezhaler 110/50?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Ultibro Breezhaler 110/50?](#)
5. [What should I know while using Ultibro Breezhaler 110/50?](#)
6. [Are there any side effects?](#)
7. [Product Details](#)

1. WHY AM I USING ULTIBRO BREEZHALER 110/50?

You may be having Ultibro Breezhaler 110/50 because you have chronic obstructive pulmonary disease (COPD). This is a serious lung problem that can cause **trouble** breathing and **non-stop** coughing.

Ultibro Breezhaler 110/50 works by keeping the lungs open. This makes it easier to breathe. It also helps stop your breathing and coughing from getting worse from time to time.

2. WHAT SHOULD I KNOW BEFORE I USE ULTIBRO BREEZHALER 110/50?

Do not use Ultibro Breezhaler 110/50 if you:

- are allergic to indacaterol maleate or glycopyrronium bromide or any of the other ingredients. These are listed at the end of this leaflet
- are breastfeeding.

Check with your doctor if you:

- have or have had any medical problems, especially the following:
 - asthma
 - heart problems
 - fits (seizures)
 - thyroid problems
 - diabetes
 - kidney problems
 - severe liver problems
 - eye problems such as narrow-angle glaucoma
 - problems passing urine

- are pregnant or are planning to have a baby. See extra information under [Pregnancy and breastfeeding](#).

While using this medicine, you may be at risk of developing certain side effects. **It is important you understand these risks and how to monitor for them.** See extra information under [side effects](#).

Pregnancy and Breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. **If you become pregnant while taking Ultibro Breezhaler 110/50 tell them as soon as possible so you can talk about the risks and benefits of using Ultibro Breezhaler 110/50 when pregnant.**

Tell your doctor if you are breastfeeding or plan to breastfeed as the doctor may need to change your medicine.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins, supplements or remedies. **Some of them may affect how Ultibro Breezhaler 110/50 works.**

For example:

- medicines used in to treat depression (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- medicines for your lung disease that are similar to Ultibro (e.g. ipratropium, oxitropium, tiotropium, eformoterol, salmeterol)
- medicines that lower the potassium in your blood. For example, diuretics (also known as "water tablets", used to treat high blood pressure, e.g. hydrochlorothiazide), medicines such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone)
- medicines used to treat high blood pressure or heart problems (e.g. propranolol) or glaucoma (e.g. timolol)

Check with your doctor or pharmacist if you are not sure about what medicines you are taking and if these medicines may affect Ultibro Breezhaler 110/50.

4. HOW DO I USE ULTIBRO BREEZHALER 110/50?

How much to use

- You need to inhale one puff of Ultibro Breezhaler 110/50 once a day every day.

- Have it at the same time each day.

Use Ultibro Breezhaler 110/50 as instructed by your doctor and until your doctor tells you to stop. Do not let anyone else use it.

Detailed instructions with diagrams on how to use Ultibro Breezhaler 110/50 are available [here](#).

If you forget to use Ultibro Breezhaler 110/50

If it is almost time for your next dose, skip the dose you missed and inhale your next dose when you are meant to. **Do not have a double dose to make up for the dose you missed.**

If you take too much (overdose)

If you think that you or anyone else may have had too much Ultibro Breezhaler 110/50, you may need urgent medical attention.

Immediately do one of the following:

- telephone the Poisons Information Centre (ph: 13 11 26) or
- go to the Emergency Department at your nearest hospital or
- phone your doctor

5. WHAT SHOULD I KNOW WHILE USING ULTIBRO BREEZHALER 110/50?

Call your doctor straight away if you:

- find that the usual dose is not giving as much relief, or does not last as long as usual.

Alcohol, driving and using machinery

Ultibro Breezhaler 110/50 may cause dizziness in some people. **See how Ultibro Breezhaler 110/50 affects you before you drive or operate any machines.**

If you drink alcohol, dizziness may be worse.

Looking after your medicine

- Follow the instructions in the carton on how to properly clean and take care of your medicine
- Store it in a cool dry place away from moisture, heat or sunlight; for example, don't store it
 - in the bathroom or near a sink
 - in the car or on window sills
- Do not use this medicine after the expiry date
- **Keep it where children cannot reach it.**
- If you no longer need to use Ultibro Breezhaler 110/50 or it is out of date, take it to any pharmacy for safe disposal.

6. ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you get any, they will mostly be minor and temporary. Getting some side effects however may mean you need to get medical help. See the information below and if you need to, ask your doctor or pharmacist to answer any questions you may have about side effects.

Speak to your doctor if you have any of the following less serious side effects and they worry you:

- Dizziness
- Headache
- Cough
- Sore throat
- Pain in the muscles, bones or joints
- Muscle spasm
- Itching and/or rash
- Dry mouth
- Feeling unwell, vomiting, diarrhea and tummy pain
- Problems falling asleep
- Pain in the arms or legs
- Hoarse voice
- Tingling or numbness
- Sore throat and runny nose together
- Feeling pressure or pain in the cheeks and forehead
- Feeling tired
- Swollen hands, ankles and feet.

Call your doctor straight away if you notice any of the following serious side effects:

- Crushing chest pain
- Extreme thirst, lots of urine, increased appetite with weight loss and tiredness
- Changes in vision such as blurred vision, visual halos or red eyes together with coloured images
- Blocked nose, sneezing, coughing, headache with or without fever
- Swollen face, lips, mouth, tongue or throat making it hard to swallow or breathe
- Tight chest, wheezing, coughing or problems breathing
- Irregular heartbeat or fast heart beat
- Nose bleeds
- Painful and frequent urination.

Tell your doctor or pharmacist if you don't feel well for any other reasons. Other side effects not listed here may happen in some people.

Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. PRODUCT DETAILS

What does Ultibro Breezhaler 110/50 look like?

- Ultibro Breezhaler 110/50: capsules: Transparent yellow cap and natural transparent body capsules containing a white to practically white powder, with

the product code "IGP110.50" printed in blue under two blue bars on body and the company logo printed in black on cap. **The capsules go inside the Breezhaler device. Do not swallow the capsules.**

- **Breezhaler:** A white plastic Breezhaler inhalation device is also supplied in the pack (AUST R 206449)

What does Ultibro Breezhaler 110/50 contain?

Active ingredient: Each capsule contains 110 micrograms of indacaterol as indacaterol maleate and 50 micrograms of glycopyrronium as glycopyrronium bromide (glycopyrrolate).

Inactive ingredients: lactose and magnesium stearate

How do I contact the supplier of this product?

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

Web site: www.novartis.com.au

This leaflet was prepared in February 2019

Appendix 3. EDWG-supplied Toujeo® CMI

TOUJEO (too-jay-oh)

Important information you need to know about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI). The CMI has more details and can be found in the [full CMI](#) over the page. If you are worried about using this medicine, ask your doctor or pharmacist.

Why am I using Toujeo ?

Toujeo is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus. For more information, [see full CMI](#)

What should I know before I use Toujeo ?

Don't use it if you have ever had an allergic reaction to insulin. Talk to your Doctor if:

1. You have diabetic ketoacidosis (often caused by high blood glucose levels)
2. You have any other medical conditions, including kidney problems or liver problems
3. You take any medicines for any other condition
4. You're pregnant or plan to become pregnant or are breast-feeding.

For more information, [see full CMI](#)

What if I'm taking other medicines ?

Some medicines may interfere with Toujeo and affect how it works on you.

For more information, [see full CMI](#)

How do I use Toujeo ?

Your doctor will tell you when and how much Toujeo you need to use each day.

For more information, [see full CMI](#).

What should I know while using Toujeo ?

Your doctor may increase or decrease your dose, depending on your blood sugar levels. It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects

For more information, [see full CMI](#).

Are there any side effects ?

Serious side effects may include hypoglycaemia or allergic reaction.

For more information on these side effects, please [see full CMI](#)

TOUJEO (too-jay-oh)

CONSUMER MEDICINE INFORMATION (CMI)

This leaflet provides important information about using Toujeo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or queries about using Toujeo.**

Where to find information in this leaflet:

1. [WHY AM I USING TOUJEO ?](#)
2. [WHAT SHOULD I KNOW BEFORE I USE TOUJEO ?](#)
3. [WHAT IF I'M TAKING OTHER MEDICINES ?](#)
4. [HOW DO I USE TOUJEO ?](#)
5. [WHAT SHOULD I KNOW WHILE USING TOUJEO ?](#)
6. [ARE THERE ANY SIDE EFFECTS ?](#)
7. [PRODUCT DETAILS](#)

1. WHY AM I USING TOUJEO?

Toujeo contains the active substance insulin glargine. Toujeo is a modified insulin that is a substitute for the insulin produced by the pancreas.

Toujeo is used to reduce high blood sugar (glucose) levels in adults with diabetes mellitus.

Toujeo is a long-acting insulin. Your doctor may tell you to use a rapid acting insulin or oral anti-diabetic medication in combination with Toujeo.

2. WHAT SHOULD I KNOW BEFORE I USE TOUJEO?

Do not use Toujeo if:

- You have ever had an allergic reaction to medicines containing insulin, or any of the ingredients listed at the end of this leaflet.
- You have diabetic ketoacidosis (often caused by high blood glucose levels)

Check with your doctor if:

- You have any other medical conditions, including any kidney problems or liver problems
- You take any medicines for any other condition
- You drink alcohol
- You don't eat regular meals
- You do a lot of exercise
- You're ill or are feeling unwell

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [are there any side effects ?](#)

Your diabetic educator will also provide you with further information about diabetes, and how to minimize side effects side effects.

Pregnancy and breast feeding

Check with your doctor if you're pregnant or intend to become pregnant. **Pregnancy may make managing your diabetes more difficult.**

Talk to your doctor if you're breastfeeding or intend to breastfeed.

3. WHAT IF I'M TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you're taking any other medicines, including any medicines that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Toujeo and affect how it works.

Medicines that may increase the blood sugar lowering effect of Toujeo include:

- oral antidiabetic medicines that are used to treat type 2 diabetes
- some blood pressure, blood flow, cholesterol and heart medications
- some medications for pain and inflammation
- some antidepressants
- certain antibiotics that contain sulfur

Medicines that may reduce the blood sugar lowering effect of Toujeo include:

- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives and gynaecological medications
- some fluid and glaucoma medications
- some medicines to treat tuberculosis and
- HIV/AIDS
- some psychiatric medications
- adrenaline and asthma medications such as salbutamol, terbutaline

Certain heart medications, especially beta-blockers, may also mask the symptoms of hypoglycaemia

Check with your doctor or pharmacist if you're not sure about what medicines you're taking and if these medicines may affect Toujeo.

4. HOW DO I USE TOUJEO?

How much to use ?

Your doctor will tell you how much Toujeo you need to use each day. Use it until your doctor tells you to stop.

Your doctor may increase or decrease the dose, depending on your blood sugar levels.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When do I use Toujeo ?

Toujeo should be used once a day, at the same time every day.

Your doctor will tell you what time of day to use Toujeo.

How do I inject Toujeo ?

Always check the label on your injection pen before injecting to make sure you are using the right insulin. Make sure that "U300" is highlighted in honey gold on the label of your injection pen.

Toujeo should be injected under the skin. Your doctor or diabetes educator will have shown you how to use Toujeo.

To avoid under-dosing or over-dosing due to blockages, **be sure you use a new needle each time you inject Toujeo.**

Do not attempt to withdraw Toujeo from the cartridge of the pre-filled pen into a syringe.

A video providing more information and demonstration on how to inject Toujeo is available at: <http://www.simple-steps.com.au>

If you forget to use Toujeo

Toujeo is a long-acting insulin and should be used regularly at the same time each day. If you miss your dose at the usual time, your blood sugar levels may become high (hyperglycaemia).

If you miss a dose and aren't sure what to do, contact your doctor or healthcare professional for specific advice.

Do NOT use a double dose of your insulin.

If you use too much Toujeo

If you think that you or anyone else may have used too much Toujeo, your blood sugar level may become too low (hypoglycaemia).

You should immediately:

- telephone the Poisons Information Centre (ph: 13 11 26)

or

- contact your doctor or nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. WHAT SHOULD I KNOW WHILE USING TOUJEO?

Measure your blood sugar level regularly.

Hypoglycaemia

Toujeo is used to reduce high blood sugar (glucose), if your blood glucose levels are reduced too much, you may experience symptoms of hypoglycaemia, also known as a "hypo". Early symptoms of mild to moderate hypoglycaemia can come on suddenly and may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or drink with you in case you start to experience any of the symptoms of hypoglycaemia.

Tell your relatives, friends, close workmates or carers that you have diabetes. **Make sure they know how to recognise the symptoms of hypoglycaemia, and that they need to get you medical help immediately if you lose consciousness.**

Tell your doctor if you often have very low blood sugar levels or hypoglycaemia or if you've ever become unconscious after using Toujeo. **Your doctor may need to adjust your dose of Toujeo or of other medicines you're taking.**

Alcohol

Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of hypoglycaemia.

Looking after your medicine

Prior to use, keep your unopened Toujeo pre-filled pens in the refrigerator where the temperature is between 2-8°C.

Before using a pre-filled pen for the first time, take the pen out of the fridge and allow it to come to room temperature for 1 to 2 hours. After use, this pre-filled pen should not be put in the refrigerator, and it should be kept below 30°C.

Do not leave pen near heat or in direct light.

Do not allow your pens to freeze. **Discard if frozen.**

Discard the pre-filled pen within 28 days of first use.

Pre-filled pens that are carried as a spare must also be discarded 28 days after being removed from the refrigerator.

Your Doctor or diabetic educator will show you to safely dispose of your needles and pre-filled pen once it is empty.

6. ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you experience them, most are minor and temporary, however some may need medical attention. Ask your doctor or pharmacist to answer any questions you may have about side effects.

Speak to your doctor if you have any of the following less serious side effects and they worry you:

- hypoglycaemia (mild to moderate)
- redness, swelling or itching at the injection site
- a depression or thickening of the skin around the injection site

Call your doctor straight away, or go straight to Accident and Emergency at your nearest hospital if you notice any of the following serious side effects:

- More severe symptoms of hypoglycaemia, including:
 - disorientation
 - seizures, fits or convulsions
 - loss of consciousness
- Signs of a serious allergic reaction, including:
 - skin rashes over a large part of the body
 - shortness of breath, wheezing
 - swelling of the face, lips or tongue
 - fast pulse
 - Sweating

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people.

Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. PRODUCT DETAILS

What does Toujeo look like ?

Toujeo comes in a pre-filled disposable pen containing a 1.5 mL cartridge of Toujeo. (Aust R 223457)

What does Toujeo contain ?

Active ingredient: insulin glargine

Inactive ingredients: meta-cresol, glycerol, zinc chloride, hydrochloric acid, sodium hydroxide, water for injection.

Who distributes Toujeo ?

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall No: 1800 818 806

This leaflet was prepared in February 2019

Appendix 4. Final user tested Plavix® CMI

Plavix (Plav-ix)

Important facts you need to know about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI). The CMI has more details and can be found in the [full CMI](#) over the page. If you are worried about using this medicine, ask your doctor or pharmacist.

Why am I taking Plavix?

Plavix is used to prevent blood clots forming in hardened blood vessels that may lead to stroke, a heart attack or even death.

For more information, see the [full CMI](#).

What should I know before I take Plavix?

Do not use Plavix if you have had an allergic reaction to it before.

Talk to your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see the [full CMI](#).

What if I am taking other medicines?

Some medicines may interfere with Plavix and affect how it works.

A list of these medicines is in the [full CMI](#).

How do I take Plavix?

The usual dose of Plavix is one 75mg tablet daily, with or without food.

More instructions can be found in the [full CMI](#).

What should I know while taking Plavix?

Remind any doctor or dentist when you visit that you are using Plavix.

Tell your doctor immediately if you become pregnant.

Do not stop taking Plavix suddenly.

Be careful driving or operating machinery until you know how Plavix affects you.

When drinking alcohol, dizziness may be worse.

For more information, see the [full CMI](#).

Are there any side effects?

Serious side effects include:

- dizziness
- unusually heavy bleeding
- bloody or black bowel motions
- nausea or vomiting
- red or purple spots visible through your skin
- itching, inflamed or cracked or red skin.

If you have any concerns about using this medicine, speak with your doctor or pharmacist or call 1800 123 456.

For more information on these side effects, please see the [full CMI](#).

Plavix* Tablets

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Plavix. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Plavix.**

Where to find information in this leaflet:

1. [Why am I taking Plavix?](#)
2. [What should I know before I take Plavix?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Plavix?](#)
5. [What should I know while I am taking Plavix?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking Plavix?

Plavix contains a medicine called clopidogrel. It belongs to a group of medicines called anti-platelet medicines that prevent the clumping of small blood cells (platelets) together during clotting.

Plavix works by preventing blood clots forming in hardened blood vessels that may lead to stroke, heart attack or death.

You may have been prescribed Plavix because:

- you have previously suffered a heart attack, stroke or have peripheral arterial disease
- you have suffered Acute Coronary Syndrome.

2. What should I know before I take Plavix?

Do not take Plavix if:

- you are allergic to clopidogrel or any ingredients listed at the end of this leaflet
- you have a medical condition causing bleeding
- you suffer from severe liver disease.

Check with your doctor if you:

- have had recent surgery (including dental surgery) or are planning to have surgery in the next two weeks
- are allergic to other antiplatelet medicines (e.g. ticlopidine, prasugrel)
- are pregnant or are planning to have a baby. See more information under [Pregnancy and breastfeeding](#)

- have or have had any medical conditions, especially the following:
 - bleeding disorders or blood clotting problems
 - any illness or disability caused by bleeding
 - recent serious injury
 - any form of liver disease.

During treatment, you may be at risk of developing certain side effects. **It is important you understand these risks and how to monitor for them.**

See additional information under [Are there any side effects?](#).

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

If you become pregnant while taking Plavix, speak with your doctor as soon as possible to discuss the possible risks and benefits of continuing to take Plavix.

Talk to your doctor if you are breastfeeding or intend to breastfeed as the doctor may need to change your medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins, supplements or remedies.

Some medicines may interfere with Plavix and affect how it works. These include:

- anticoagulant and anti-platelet medicines such as aspirin, heparin and warfarin
(note, your doctor may prescribe aspirin with Plavix if you have Acute Coronary Syndrome)
- non-steroidal anti-inflammatory drugs
- medicines for stomach ulcers or reflux disease
- medicines for gastric reflux (e.g. omeprazole)
- phenytoin for epilepsy
- tolbutamide for diabetes
- tamoxifen for breast cancer
- fluvastatin to lower cholesterol
- some antidepressant medicines.

Check with your doctor or pharmacist if you are not sure about what medicines you are taking and if these medicines may affect Plavix.

4. How do I take Plavix?

How much to take

- The usual dose of Plavix is one 75 mg tablet daily with or without food.
- Swallow with a glass of water or other liquid.
- If you are prescribed Plavix for the treatment of Acute Coronary Syndrome, you may receive a starting dose of 300 mg, then one 75 mg tablet daily.

Take Plavix as prescribed by your doctor and until your doctor tells you to stop.

Do not give this medicine to anyone else.

If you forget to take Plavix

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. **Do not take a double dose to make up for the dose you missed.**

If you take too much (overdose)

If you think that you or anyone else may have taken too much Plavix, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital, or
- contact your doctor.

5. What should I know while I am taking Plavix?

Bleeding and Plavix

Sometimes bleeding may occur in your body while you are taking Plavix or it may take longer to stop bleeding.

To manage your risk you should:

- tell all doctors, dentists, nurses and pharmacists treating you that you are taking Plavix (e.g. surgery or dental work)
- ask your doctor about any activities to avoid (e.g. sport)
- have any blood tests your doctor orders.

Call your doctor straight away if you have:

- an injury or are injured
- abnormal bruising or bleeding
- abnormal nose bleeds
- bloody or black bowel motions
- red or purple blotches on your skin.

If you are taking both aspirin and Plavix, your risk of bleeding may be increased.

Alcohol, driving and using machinery

Plavix may cause faintness or dizziness in some people.

Be careful driving or operating machinery until you know how Plavix affects you.

If you drink alcohol, faintness or dizziness may be worse.

Looking after your medicine

Do not start a new packet if the packaging is torn or shows signs of being opened.

Do not take the tablets after the expiry date on the pack has passed.

Keep tablets in the blister pack until it is time to take them.

Store your Plavix in a cool, dry place where the temperature stays below 25°C.

Keep your tablets where young children cannot reach them.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Ask your doctor or pharmacist if you have any questions about side effects.

Less serious side effects	What to do
<ul style="list-style-type: none"> • diarrhoea • itching • pain or stiffness in the joints • things taste different 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects	What to do
<p>Allergic reaction or skin-related:</p> <ul style="list-style-type: none"> • chest tightness, wheezing, coughing or difficulty breathing • swelling of the face, lips, mouth, tongue or throat causing difficulty in swallowing or breathing • rash or hives • red or purple spots visible through your skin • itching, inflamed, cracking or red skin 	<p>Call your doctor straight away if you notice any of these serious side effects.</p>

Serious side effects	What to do
Bleeding-related: <ul style="list-style-type: none"> • bloody or black bowel motions • diarrhoea with blood, mucus, stomach pain and fever • vomiting of blood or vomit that looks like coffee grounds • coughing up blood • blood in the eyes • blood in your urine • unusually heavy bleeding from cuts or wounds • bleeding (including nose bleeds) or bruising more easily than normal • unusually heavy or unexpected menstrual bleeding 	Call your doctor straight away if you notice any of these serious side effects.

Serious side effects	What to do
More broad or affecting different parts of the body: <ul style="list-style-type: none"> • nausea or vomiting • abdominal or stomach pain • numbness or problems with coordination • faintness, dizziness, light-headedness or blurred vision • slurred speech or other difficulty in speaking • headache (severe and continuing), confusion or hallucinations • fever or other signs of infection • chills, sweating or clammy skin, fever, muscle weakness or pain, loss of appetite and fatigue • anaemia (tired and looking pale) • weight loss • yellowing of the skin or whites of the eyes, pale stools and dark urine with vomiting and stomach pain 	Call your doctor straight away if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

You can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Plavix looks like

- Plavix 75 mg tablets are pink round tablets with '75' engraved on one side and '1171' on the other. A box contains 28 tablets. (AUST R 78622)
- Plavix 300 mg tablets are pink oblong tablets with '300' engraved on one side and '1332' on the other. A box contains 30 tablets. (AUST R 151257)

What Plavix contains

Active ingredient:	clopidogrel
Inactive ingredients:	mannitol, macrogol 6000, microcrystalline cellulose, hydrogenated castor oil, hydroxypropylcellulose, hypromellose, lactose, titanium dioxide, glycerol triacetate, red iron oxide, carnauba wax.

Do not take this medicine if you are allergic to any of these ingredients.

Who distributes Plavix

Sanofi-Aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park
NSW 2113
Telephone: 1800 818 806

This leaflet was prepared in May 2019.

Appendix 5. Final user tested Ultibro® CMI

Ultibro Breezhaler 110/50 Capsules

Important facts you need to know about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI). The [full CMI](#) over the page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ultibro Breezhaler 110/50?

Ultibro Breezhaler 110/50 is used for treating chronic obstructive pulmonary disease, also called COPD.

For more information, see [1. Why am I using Ultibro Breezhaler 110/50?](#) in the full CMI.

2. What should I know before I use Ultibro Breezhaler 110/50?

Do not use Ultibro Breezhaler 110/50 if you have had an allergic reaction to it before.

Talk to your doctor if you:

- have any other medical conditions
- take medicines for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see [2. What should I know before I use Ultibro Breezhaler 110/50?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may affect how Ultibro Breezhaler 110/50 works.

A list of these medicines is in the section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ultibro Breezhaler 110/50?

- Ultibro Breezhaler 110/50 capsules need to be put into the Breezhaler device so that you can inhale the powder in the capsule through it.
- You need to inhale one puff of Ultibro Breezhaler 110/50, once every day.
- Do not swallow the capsules.

More instructions can be found in the section [4. How do I use Ultibro Breezhaler 110/50?](#) in the full CMI.

5. What should I know while using Ultibro Breezhaler 110/50?

Things you should do	<ul style="list-style-type: none"> • Call your doctor straight away if you find that the usual dose is not giving as much relief, or does not last as long as usual. • Tell your doctor immediately if you become pregnant. • Remind any doctor or dentist when you visit that you are using Ultibro Breezhaler 110/50.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using Ultibro Breezhaler 110/50 suddenly.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or using machines or tools until you know how Ultibro Breezhaler 110/50 affects you.
Drinking alcohol	<ul style="list-style-type: none"> • When drinking alcohol, dizziness may be worse.

For more information, see [5. What should I know while using Ultibro Breezhaler 110/50?](#) in the full CMI.

6. Are there any side effects?

The most serious side effects that some people have had are:

- feeling breathless
- chest feeling tight
- wheezing
- cough
- pain or uncomfortable feeling in the eyes.

For more information on side effects and what to do if you have any, see [6. Are there any side effects?](#) in the full CMI.

Ultibro Breezhaler 110/50* Capsules

Consumer Medicine Information (CMI)

This leaflet has important information about using Ultibro Breezhaler 110/50.

Speak to your doctor or pharmacist if you want more information or if you have any concerns about using Ultibro Breezhaler 110/50.

Where to find information in this leaflet:

1. [Why am I using Ultibro Breezhaler 110/50?](#)
2. [What should I know before I use Ultibro Breezhaler 110/50?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Ultibro Breezhaler 110/50?](#)
5. [What should I know while using Ultibro Breezhaler 110/50?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Ultibro Breezhaler 110/50?

You may be having Ultibro Breezhaler 110/50 because you have chronic obstructive pulmonary disease (COPD). This is a serious lung problem that can cause **trouble** breathing and **non-stop** coughing.

Ultibro Breezhaler 110/50 works by keeping the lungs open. This makes it easier to breathe. It also helps stop your breathing and coughing from getting worse.

2. What should I know before I use Ultibro Breezhaler 110/50?

Do not use Ultibro Breezhaler 110/50 if you:

- are allergic to indacaterol maleate or glycopyrronium bromide or any of the other ingredients listed at the end of this leaflet
- are breastfeeding.

Check with your doctor if you:

- have or have had any medical conditions, especially:
 - asthma
 - heart problems
 - fits (seizures)
 - thyroid problems
 - diabetes
 - kidney problems
 - severe liver problems
 - eye problems such as narrow-angle glaucoma
 - problems passing urine
- are pregnant or are planning to have a baby (see extra information under [Pregnancy and breastfeeding](#)).

While using this medicine, you may be at risk of developing certain side effects. **It is important you understand these risks and how to monitor for them.**

See extra information under [6. Are there any side effects?](#).

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

If you become pregnant while using Ultibro Breezhaler 110/50, tell them as soon as possible so you can talk about the risks and benefits of using this medicine when pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed as they may need to change your medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins, supplements or remedies.

Some of them may affect how Ultibro Breezhaler 110/50 works. For example:

- medicines used in to treat depression (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- medicines for your lung disease that are similar to Ultibro Breezhaler 110/50 (e.g. ipratropium, oxitropium, tiotropium, eformoterol, salmeterol)
- medicines that lower the potassium in your blood (e.g. diuretics (also known as "water tablets", used to treat high blood pressure, e.g. hydrochlorothiazide), medicines such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone))
- medicines used to treat high blood pressure or heart problems (e.g. propranolol) or glaucoma (e.g. timolol).

Check with your doctor or pharmacist if you are not sure about what medicines you are taking and if these medicines may affect Ultibro Breezhaler 110/50.

4. How do I use Ultibro Breezhaler 110/50?

Ultibro Breezhaler 110/50 capsules need to be put into the Breezhaler device so that you can inhale the powder in the capsule through it.

Detailed instructions with diagrams on how to use Ultibro Breezhaler 110/50 are available online at http://medicines.org.au/files/media/Ultibro_How%20to%20Use.pdf.

Do not swallow the capsules.

How much to use

- You need to inhale one puff of Ultibro Breezhaler 110/50, once a day every day.
- Have it at the same time each day.

Use Ultibro Breezhaler 110/50 as instructed by your doctor and until your doctor tells you to stop.

If you forget to use Ultibro Breezhaler 110/50

If it is almost time for your next dose, skip the dose you missed and inhale your next dose when you are meant to. **Do not have a double dose to make up for the dose you missed.**

If you use too much (overdose)

If you think that you or anyone else may have had too much Ultibro Breezhaler 110/50, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital, or
- contact your doctor.

5. What should I know while using Ultibro Breezhaler 110/50?

Things you should do

Call your doctor straight away if you:

- find that the usual dose is not giving as much relief, or does not last as long as usual.
- become pregnant.

Remind any doctor or dentist when you visit that you are using Ultibro Breezhaler 110/50.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not let anyone else use your Ultibro Breezhaler 110/50.

Driving or using machines

Ultibro Breezhaler 110/50 may cause dizziness in some people. **Be careful before you drive or use any machines or tools until you know how Ultibro Breezhaler 110/50 affects you.**

Drinking alcohol

If you drink alcohol, dizziness may be worse.

Looking after your medicine

Follow the instructions in the carton on how to properly clean and take care of your medicine.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
More broad or affecting different parts of the body: <ul style="list-style-type: none"> cough dry mouth hoarse voice sore throat sore throat and runny nose together dizziness feeling tired feeling unwell, vomiting, diarrhoea and tummy pain swollen hands, ankles and feet problems falling asleep itching and/or rash 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Muscle or pain-related: <ul style="list-style-type: none"> headache pain in the muscles, bones or joints pain in the arms or legs feeling pressure or pain in the cheeks and forehead muscle spasm tingling or numbness 	

Serious side effects

Serious side effects	What to do
<p>More broad or affecting different parts of the body:</p> <ul style="list-style-type: none"> • crushing chest pain • irregular heartbeat or fast heartbeat • changes in vision such as blurred vision, visual halos or red eyes together with coloured images • extreme thirst, lots of urine, increased appetite with weight loss and tiredness • painful and frequent urination • blocked nose, sneezing, coughing, headache with or without fever • nose bleeds <p>Allergic reaction or breathing-related:</p> <ul style="list-style-type: none"> • tight chest, wheezing, coughing or problems breathing • swollen face, lips, mouth, tongue or throat making it hard to swallow or breathe 	<p>Call your doctor straight away if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you do not feel well for any other reasons.

Other side effects not listed here may happen in some people.

Reporting side effects

You can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.

7. Product Details

This medicine is only available with a doctor's prescription.

What Ultibro Breezhaler 110/50 looks like

- Ultibro Breezhaler 110/50 capsules:**

Transparent yellow cap and natural transparent body capsules containing a white to practically white powder, with the product code "IGP110.50" printed in blue under two blue bars on body and the company logo printed in black on cap.



- Breezhaler:**

A white plastic Breezhaler inhalation device is also supplied in the pack (AUST R 206449).

**What Ultibro Breezhaler 110/50 contains**

Active ingredient (main ingredient)	<p>Each capsule contains:</p> <ul style="list-style-type: none"> • 110 micrograms of indacaterol as indacaterol maleate, and • 50 micrograms of glycopyrronium as glycopyrronium bromide (glycopyrrolate).
Other ingredients (inactive ingredients)	lactose and magnesium stearate

Do not use this medicine if you are allergic to any of these ingredients.

Who distributes Ultibro Breezhaler 110/50

Novartis Pharmaceuticals Australia Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113
Telephone 1800 671 203
Website: www.novartis.com.au

This leaflet was prepared in May 2019.

Appendix 6. Final user tested Toujeo® CMI

Toujeo* (too-jay-oh)



Important information you need to know about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI).

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Toujeo?

Toujeo is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

For more information, see Section [1. Why am I using Toujeo](#) in the full CMI.

2. What should I know before I use Toujeo?

Do not use it if you have ever had an allergic reaction to insulin.

Talk to your doctor if you:

- have diabetic ketoacidosis (often caused by high blood sugar levels)
- have any other medical conditions, including kidney problems or liver problems
- take any medicines for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Toujeo](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Toujeo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines](#) in the full CMI.

4. How do I use Toujeo?

- Toujeo should be injected under the skin. Your doctor will tell you when and how much Toujeo you need to use each day.
- A video providing information on how to inject Toujeo is available at: <http://www.simple-steps.com.au>
- Your doctor may change your dose, depending on your blood sugar levels.
- Use Toujeo until your doctor tells you to stop. Too much or too little insulin can cause serious effects.

More instructions can be found in Section [4. How do I use Toujeo](#) in the full CMI.

5. What should I know while using Toujeo?

Things you should do	<ul style="list-style-type: none"> • It is very important that you manage your diabetes carefully. Measure your blood sugar level regularly. • Tell your doctor if you often have low blood sugar levels or have ever become unconscious after using Toujeo. • Always carry sugary food or drink with you in case you start to have any symptoms of low blood sugar. • Remind any doctor or dentist you visit that you are using Toujeo.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Drinking alcohol may mask the symptoms of low blood sugar.
Looking after your medicine	<ul style="list-style-type: none"> • Keep unopened Toujeo pre-filled pens in the fridge where the temperature is between 2-8°C. Do not freeze. • Before using a new pre-filled pen, take it out of the fridge and let it come to room temperature for 1-2 hours. • After you have started using a pre-filled pen, do not put it back in the fridge. Keep it at room temperature below 30°C, away from direct heat and light. • Discard within 28 days any pre-filled pen you have started using or any spare pen taken out of the fridge.

For more information, see Section [5. What should I know while using Toujeo](#) in the full CMI.

6. Are there any side effects?

Serious side effects may include low blood sugar (hypoglycaemia) or an allergic reaction.

For more information on these side effects and what to do if you have any side effects, see Section

[6. Are there any side effects](#) in the full CMI.

Toujeo*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Toujeo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or queries about using Toujeo.**

Where to find information in this leaflet:

1. [Why am I using Toujeo?](#)
2. [What should I know before I use Toujeo?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Toujeo?](#)
5. [What should I know while using Toujeo?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Toujeo?

Toujeo contains the active ingredient insulin glargine. Toujeo is a modified insulin that is a substitute for the insulin produced by your pancreas.

Toujeo is used to reduce high blood sugar (glucose) levels in adults with diabetes mellitus.

Toujeo is a long-acting insulin. Your doctor may tell you to use a rapid-acting insulin or oral anti-diabetic medication in combination with Toujeo.

2. What should I know before I use Toujeo?

Do not use Toujeo if:

- you have ever had an allergic reaction to medicines containing insulin, or any of the ingredients listed at the end of this leaflet
- you have diabetic ketoacidosis (often caused by high blood sugar levels).

Check with your doctor if you:

- have any other medical conditions, including any kidney problems or liver problems
- take any medicines for any other condition
- drink alcohol
- do not eat regular meals
- do a lot of exercise
- are ill or are feeling unwell.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Your diabetes educator can provide further information about diabetes and how to minimise side effects.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Pregnancy may make managing your diabetes more difficult.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Toujeo and affect how it works.

Medicines that may increase the blood sugar lowering effect of Toujeo include:

- oral anti-diabetic medicines that are used to treat type 2 diabetes
- some blood pressure, blood flow, cholesterol and heart medications
- some medications for pain and inflammation
- some antidepressants
- certain antibiotics that contain sulfur.

Medicines that may reduce the blood sugar lowering effect of Toujeo include:

- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives and gynaecological medications
- some fluid and glaucoma medications
- some medicines to treat tuberculosis and HIV/AIDS
- some psychiatric medications
- adrenaline and asthma medications such as salbutamol, terbutaline.

Medicines that may mask the symptoms of low blood sugar (hypoglycaemia) include:

- certain heart medications, especially beta-blockers.

Check with your doctor or pharmacist if you are not sure about what medicines you are taking and if these medicines may affect Toujeo.

4. How do I use Toujeo?

How much to use

- Your doctor will tell you how much Toujeo you need to use each day.
- Follow the instructions provided and use Toujeo until your doctor tells you to stop.
- Your doctor may change your dose, depending on your blood sugar levels.

When to use Toujeo

- Toujeo should be used once a day, at the same time every day.
- Your doctor will tell you what time of day to use Toujeo.

How to inject Toujeo

- Always check the label on your Toujeo pre-filled pen before using it to make sure you have the correct insulin.
- Make sure that "U300" is highlighted in honey gold colour on the label of your Toujeo pre-filled pen.
- **Use a new needle each time you inject Toujeo.** This helps to avoid under-dosing or over-dosing due to blockages.
- Toujeo should be injected under the skin. Your doctor or diabetes educator will have shown you how to use Toujeo.
- **Do not try to withdraw Toujeo from the cartridge of the pre-filled pen into a syringe.**

A video providing more information and a demonstration on how to inject Toujeo is available at:
<http://www.simple-steps.com.au>

If you forget to use Toujeo

Toujeo is a long-acting insulin and should be used regularly at the same time each day. If you miss your dose at the usual time, your blood sugar levels may become high (hyperglycaemia).

If you miss a dose and are not sure what to do, contact your doctor or pharmacist for specific advice.

Do not use a double dose of your insulin.

If you use too much Toujeo

If you think that you have used too much Toujeo, your blood sugar level may become too low (hypoglycaemia). You may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Toujeo?

Things you should do

Measure your blood sugar level regularly.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

Tell your doctor if you often have low blood sugar levels or if you have ever become unconscious after using Toujeo.

Your doctor may need to adjust your dose of Toujeo or of other medicines you are taking.

Remind any doctor or dentist you visit that you are using Toujeo.

Tell your relatives, friends, close workmates or carers that you have diabetes.

Hypoglycaemia (low blood sugar) and what to do

You may experience symptoms of low blood sugar (also known as a "hypo" or hypoglycaemia) if your blood sugar levels are reduced too much.

Early symptoms of mild to moderate hypoglycaemia can come on suddenly and may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heartbeat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea.

Always carry some sugary food or drink with you.

If you start to get any symptoms of low blood sugar:

- **have some sugary food or drink, and**
- **follow up with extra carbohydrates once the initial symptoms have stopped.**

Make sure people close to you know how to recognise the symptoms of low blood sugar, and that they need to get you medical help immediately if you become unconscious.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia.

Looking after your medicine

- Keep unopened Toujeo pre-filled pens in the fridge where the temperature is between 2-8°C. Do not freeze.
- Before using a new pre-filled pen, take it out of the fridge and let it come to room temperature for 1 to 2 hours.
- After you have started using a pre-filled pen, do not put it back in the fridge. Keep it at room temperature below 30°C, away from direct heat and light.

When to discard your medicine

Discard within 28 days any pre-filled pen you have started using or any spare pen taken out of the fridge.
Discard any pens that are frozen.

Getting rid of any unwanted medicine

Your doctor, pharmacist or diabetes educator will show you how to safely dispose of your needles and pre-filled pens once they are empty.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Low blood sugar-related: <ul style="list-style-type: none"> hypoglycaemia (mild to moderate) – a list of early symptoms of hypoglycaemia can be found in Section 5. What should I know while using Toujeo? Injection site-related: <ul style="list-style-type: none"> redness, swelling or itching at the injection site Hollowing or thickening of the skin around the injection site. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Low blood sugar-related: <ul style="list-style-type: none"> more severe symptoms of hypoglycaemia, including: <ul style="list-style-type: none"> disorientation seizures, fits or convulsions loss of consciousness Allergic reaction-related: <ul style="list-style-type: none"> skin rashes over a large part of the body shortness of breath, wheezing swelling of the face, lips or tongue fast pulse sweating. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

You can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Toujeo looks like

Toujeo comes in a pre-filled disposable pen containing a 1.5 mL cartridge of Toujeo (Aust R 223457).

**What Toujeo contains**

Active ingredient (main ingredient)	insulin glargine
Other ingredients (inactive ingredients)	meta-cresol, glycerol, zinc chloride, hydrochloric acid, sodium hydroxide, water for injection

Who distributes Toujeo

Sanofi-Aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Telephone: 1800 818 806

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