Australian Government

Department of Health
Therapeutic Goods Administration

Consumer Medicine Information (CMI)
How to use the improved CMI template

Version 1.0 | August 2019

TGA Health Safety Regulation

About this document

Purpose of this document

This document outlines how to communicate effectively with consumers using the revised Consumer Medicine Information (CMI) template developed through usability testing with consumers and seeking input from key stakeholders.

These guidelines on how to use the CMI template provide short form guidance on how to use the CMI template including key communication principles and tips and tricks on using the revised template. Further resources are in development and will be made available.

Audience

This document is intended for industry stakeholders involved in the writing and development of CMI.

Please note:

These guidelines are designed for use with the improved CMI template but the key communication principles are relevant to any CMI format and other consumer-oriented communications..

Writers and developers of CMI documents will need to ensure compliance with Schedules 12 and 13 of the *Therapeutic Goods Regulations 1990*.

Contents

Other essentials for writing CMI

In addition to the principles and examples used in this guide, the following are essential to developing CMI documents:

1 These guidelines relate to the ***Therapeutic Goods Regulations 1990.*** Writers should refer to Schedule 12 and Schedule 13 for all sections of the CMI for prescription and pharmacist-only medicines, respectively. For more information visit: https://www.legislation.gov.au/Series/F1996B00406

🏛 *This symbol indicates reference to specific parts of the Regulations where further information about CMI content can be found.*

2 These Guidelines are intended to be used with ***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.

📖 *This symbol tells you which section to go to in* Writing about medicines for people *to find more extensive guidance.*

3 User test new CMI or changes to existing CMI, with consumers, to ensure that those documents communicate information effectively to consumers. The principles and examples used in this guide are high-level guidance for writing CMI and do not replace the need for further evaluation of the effectiveness of CMI in communicating understandable and actionable medicine information.

4 Keep the CMI summary to one page to ensure the most important and relevant information is provided to consumers upfront for easy access. Use the links in the CMI summary page to refer consumers to the full CMI if they require further and more detailed information.

Part 1

Key communication principles

This section outlines five key principles for effectively writing CMI documents using the improved template.

How to: Using the principles

The example below explains how each principle page is laid out.

Learn what this principle means as features of your message.

See the features in practice

PRINCIPLE 1   **Keep your message clear and to the point**

Because of this we
- Use **plain English** in your writing by:
  - Using short sentences and paragraphs
  - Using common words
  - Being direct
- Provide **a plain language explanation** of necessary medical terms. Don't assume a person using a medicine has knowledge of their condition or the medicine they are taking.
- Use **active voice** rather than passive voice in the CMI document, to support consumers to take action.
- **Minimise the use of acronyms** whenever possible. Many people scan CMI for the information they want rather than reading it from top to bottom, therefore acronyms spelled out earlier in the document may get missed and cause confusion if found only in acronym form later in the document.

Because of this we avoid
- **Using medical terminology** without a plain English explanation when communicating with consumers as it can lead to confusion, disengagement with the content which could result in overlooking important information.
- Using **unnecessarily complicated words or phrases** as this can confuse consumers.

Examples

Plain English
Contact your doctor if you are taking other medicines, vitamins or supplements.

Plain language explanation
- *Active ingredient: Ingredient(s) that make the medicine work*
- *Hypoglycaemia: Low blood sugar.*

Active voice
Discard any medicine that is frozen (rather than, frozen medicine should be discarded).

Examples

Complicated words
'Non-steroidal anti-inflammatory'
'Gastrointestinal'

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Learn what to avoid when applying this principle in your message.

See unhelpful features in practice

Our communication principles

The communication principles below provide a foundation for user-centred content. You can use this page as a quick reference checklist.

The five principles

PRINCIPLE
1
Keep your message clear and to the point

When you use short sentences, plain English and action-oriented language, consumers will better understand your messages and know what they need to do.

PRINCIPLE
2
Use suitable language for the consumer

Most consumers don't understand medical language and find it confusing. Using language that is easily understood will help improve their understanding about their medicine.

PRINCIPLE
3
Use consistent language and messaging

When you use the same words for the same thing, people can find what they are looking for, they will retain the information more easily.

PRINCIPLE
4
Provide information that helps consumers make safe and appropriate decisions

Too much information confuses consumers and potentially hides key information. Targeted information with important messages first helps consumers make safe and appropriate decisions.

PRINCIPLE
5
Set out information to support findability, understanding and action

Structuring information using headings, bold type, tables and setting it out with white space on the page helps consumers to find what they need quickly.

PRINCIPLE
1

Keep your message clear and to the point

Because of this we

- Use **plain English** in writing by:
    - Using short sentences and paragraphs
    - Using common words
    - Being direct

- Provide **a plain language explanation** of necessary medical terms**.** Don't assume a person using a medicine has knowledge of their condition or the medicine they are taking.

- Use **active voice** rather than passive voice in the CMI document, to support consumers to take action.

- **Minimise the use of acronyms** whenever possible. Many people scan CMI for the information they want rather than reading it from top to bottom, therefore acronyms spelled out earlier in the document may get missed and cause confusion if found only in acronym form later in the document.

Because of this we avoid

- **Using medical terminology** without a plain English explanation when communicating with consumers as it can lead to confusion, and disengagement with the content which could result in overlooking important information.

- Using **unnecessarily complicated words or phrases** as this can confuse consumers.

Examples

Plain English
Contact your doctor if you are taking other medicines, vitamins or supplements.

Active voice
Discard any medicine that is frozen (rather than, frozen medicine should be discarded).

Plain language explanation
- *Active ingredient: Ingredient(s) that make the medicine work*
- *Hypoglycaemia: Low blood sugar.*

Examples

Complicated words
'Non-steroidal anti-inflammatory'
'Gastrointestinal'

Use suitable language for the consumer

Because of this we

- Use **pronouns** to direct your message to the consumer.

- Use **common terms for medicine types and medical conditions,** where appropriate, to aid understanding.

- Use **examples of everyday items or concepts** to explain or replace medical terminology and aid understanding, e.g. the use of the term 'crushing' chest pain helps consumers understand the condition and highlights the severity of the side effect.

- **Use images or diagrams of the medicine** to help consumers to ensure they are taking the correct medicine by being able to view medicine packaging and the dosage form (e.g. tablet, liquid, injectable).

Because of this we avoid

- Speaking in **the third person** when addressing the consumer. Using third person creates distance and unnecessary formality.

- Using **official medical classifications** without supporting plain English explanations to define medicine types or medical conditions. This is not an effective way to communicate information to consumers, as they may miss critical information that applies to them if they do not recognise or understand the terminology used.

- **Using upper case in headings** for emphasis can be seen as heavy handed and aggressive.

Examples

Pronouns
- *In section headings: 1. Why am I using [the medicine]?*
- *In body text: Tell your doctor immediately if you become pregnant.*
- *"you will need to…"*

Common terms
- *Medicine type: Medicines that treat depression*
- *Medical condition: This medicine is used to treat a lung problem that can cause trouble breathing and non-stop coughing.*

Everyday items or concepts
- *Vomiting of blood, or vomiting that looks like coffee grounds.*

Examples

Third person
- *Consumers should tell the doctor immediately if they become pregnant.*
- *"Consumers will need to…"*

Upper case in headings
- *6. ARE THERE ANY SIDE EFFECTS?*

**PRINCIPLE
3**

Use consistent language and messaging

Because of this we

- Use **consistent messages between the summary and full CMI** to aid clarity and retention, and ensure consumers know where to find information in the full CMI.

- Ensure **consistent expression** of information within the CMI document.

- Provide **medicine specific information** to consumers, e.g. side effects or overdose information.

- Ensure **appropriate information** has been included **under the relevant section** and where the consumer would expect to find this information.

Because of this we avoid

- **Unnecessarily repeating information across multiple sections of the CMI document.** This can confuse consumers, as they no longer have a clear framework to understand where to find certain information within the CMI.

- Using **inconsistent expressions to describe a similar or related message. This** can confuse consumers about the best action to take in that situation. It can also raise unnecessary cautions if consumers perceive certain phrases are meant to communicate greater severity when this was not the intention.

Examples

Medicine specific information
- *Keep unopened [name of medicine] pre-filled pens in the fridge where the temperature is between 2-8°C. Do not freeze.*

Examples

Unnecessarily repeating information
- *Warnings for pregnancy and breastfeeding are repeated in multiple locations within the CMI.*

<table>
<tr><td>PRINCIPLE
4</td><td></td></tr>
</table>

Provide information that helps consumers make appropriate decisions

Because of this we

- Provide **targeted information** that directly relates to a person or their situation so they can take action or make a decision.

- Provide **step-by-step guidance** where consumers need to know how to complete a task. Ensure all steps are within the relevant section, rather than split across sections.

- Provide **the most important information higher up in the relevant CMI section**. Then follow up with supporting information if necessary. Consumers expect critical information to be up-front.

- **Explain the why** to help consumers understand why they should act or make a decision. e.g. why not to stop taking a medicine suddenly.

Because of this we avoid

- Giving **excessive information** that does not directly relate to consumers, the medicine, or the immediate content as it can cause disengagement with the CMI document.

- Providing **irrelevant information** that does not help consumers make a decision or take action regarding the medicine

- **Breaking up steps across different sections**, as it can mean that consumers miss critical steps when taking their medicine.

- Providing **generic or vague** statements without tangible details or evidence. Consumers are less likely to act on content they view as generic or only necessary for legal purposes.

Examples

Targeted information
- *Contact your doctor straight away if you notice any of these serious side effects.*

Step by step guidance
1. *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.*
2. *Check the label on the pen to ensure you have the correct insulin, etc….*

Most important information first
- *[Name of medicine] prevents blood clots forming in your arteries.*

Explain the why
- *Tell your doctor if you drink alcohol, as alcohol may mask symptoms of low blood sugar.*
- *Do not use a double dose of your insulin. Too much insulin can cause serious side effects.*

Examples

Irrelevant information
- *You may wish to keep this leaflet to read again.*

Generic or vague
- *Store medicine in a cool, dry place.*
- *Dispose of medicine after the expiry date.*

Set out information to support findability, understanding and action

Because of this we

- Ensure **action information is highly visible** to consumers, by ensuring the call to action is:
  - In tables or at the beginning of related information
  - **Bolded in black for important** information
  - Short and to the point
- **Use meaningful subheadings, bullet points and tables** to aid scanning and navigation through the document.
- **Provide direct information on where links go and use short URL links** to external information. Links need to go directly to the relevant content – and not require additional navigation.

Because of this we avoid

- **Overusing bolded text** as it causes consumers to skim information, missing key details. It can also cause consumers to disregard critical information.
- Using **long sentences as calls to action** or burying action in dense text, as this can obscure the meaning of information or make action information difficult to locate.
- **Using long or generic URLs as links** to external information as it can make it difficult for people to access information, especially when using the paper-based CMI document.

Examples

Meaningful subheadings
- *Looking after your medicine*
- *Drinking alcohol*
- *Getting rid of unwanted medicine*

Information on where links go and use short URL links
A video providing more information and a demonstration on how to inject [name of medicine] is available at: http://www.simple-steps.com.au

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

Examples

Overusing bolded text
If you are unsure about any medicine you are taking you should check with your doctor or pharmacist. They will have more information on medicines to be careful with or avoid.

Long or generic URLs
- *Long URLs: http://medicines.org.au/files/media/ Ultibro_How%20to%20Use.pdf*
- *Generic URLs: Click here for more information.*

Part 2

CMI template tips and tricks

This section uses annotated screenshots of the improved CMI template to demonstrate where and how the communication principles may be used.

Using the annotated walkthrough

The pages shown below are screen shots of the paper based version. In the following section, these pages are used to demonstrate the tips and tricks to completing the template.

Quick annotated tips for using the template

The page in the improved CMI template where this guidance is relevant

CMI Summary – page 1

Provide **medicine brand name** in the title of the CMI Summary.

The asterix (*) should be replaced with trademark symbols as appropriate.

[medicine name]*

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

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details. [Include if applicable]
WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine. [Include if applicable]

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 you have 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 other medicines, or 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	• 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	• Do not stop using this medicine suddenly [if relevant] • [insert other relevant key point(s)]
Driving or using machines	• Insert relevant information regarding any warnings to consider before driving or operating machinery • [insert other relevant key point(s)]
Drinking alcohol	• Insert relevant statement regarding drinking alcohol while using the medicine • [insert other relevant key point(s)]
Looking after your medicine	• 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 [medicine name]? 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, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

[medicine name]*   1

Communication principles most relevant for this CMI page.

1 Keep your message clear and to the point

2 Use suitable language for the consumer

3 Use consistent language and messaging

4 Provide information that helps consumers make safe and appropriate decisions

5 Set out information to support findability, understanding and action

Related guidelines in *Writing About Medicines for People*

Refer to **Module 4** for further detail on how to structure the title section and headings.

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Include these statements regarding **Black Triangle** and **boxed warnings** if applicable

Number each heading and match with the heading in the full CMI to support document navigation

Insert **medicine name** into the relevant headings

Summary must be kept to **one page only**. The summary is intended to be provided with the full CMI and therefore is not required to be comprehensive. Only the most important and relevant information should be included in this section.

Tabulate key points in this section to aid scanning of summary page.

Add other relevant subheadings in their own rows as appropriate

Present **same key points** under **same headings** and **subheadings** in summary and full CMI.

Communication principles most relevant for this CMI page.

Where in the *Writing About Medicines for People* you can find additional guidelines

CMI Summary – page 1

Provide **medicine brand name** in the title of the CMI Summary.

The asterix (*) should be replaced with trademark symbols as appropriate.

Number each heading and match with the heading in the full CMI to support document navigation.

Summary must be kept to **one page only**. The summary is intended to be provided with the full CMI and therefore is not required to be comprehensive. Only the most important and relevant information should be included in this section.

[medicine name]*

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

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details. [Include if applicable]
WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine. [Include if applicable]

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 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 other medicines, or 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	• 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	• Do not stop using this medicine suddenly (if relevant). • [Insert other relevant key point(s)]
Driving or using machines	• Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	• Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	• 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, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

[medicine name]*   1

Include these statements regarding **Black Triangle** and **boxed warnings** if applicable.

Insert **medicine name** into the relevant headings

Tabulate key points in this section to aid scanning of summary page.

Add other relevant subheadings in their own rows as appropriate

Present **same key points** under **same headings and subheadings** in summary and full CMI.

Communication principles most relevant for this CMI page.

1	Keep your message clear and to the point
2	Use suitable language for the consumer
3	**Use consistent language and messaging**
4	Provide information that helps consumers make safe and appropriate decisions
5	**Set out information to support findability, understanding and action**

Related guidelines in *Writing About Medicines for People*

Refer to **Module 4** for further detail on how to structure the title section and headings.

Full CMI – page 2

Communication principles most relevant for this CMI page.

1 Keep your message clear and to the point

2 Use suitable language for the consumer

3 Use consistent language and messaging

4 Provide information that helps consumers make safe and appropriate decisions

5 Set out information to support findability, understanding and action

Related guidelines in *Writing About Medicines for People*

Refer to **Module 4** for further detail on how to structure the title section and headings.

Refer to **Module 7** for further detail on writing content for this section: *2. What should I know before I use [medicine name]?*

Refer to **Schedule 12** of the regulations for further detail on precautions.

Provide **medicine brand name** in the title of the full CMI.

The asterix (*) should be replaced with trademark symbols as appropriate.

List links to other sections in the full CMI to improve document navigation.

Subheading **"Warnings"** in bold at the top of this section highlights key information and aids in scanning.

Use **plain English** and provide plain language explanations.

For example: Contact your doctor if you are taking other medicines, vitamins, or supplements.

Include **Black Triangle** statement and/or **boxed warnings** if applicable an in accordance with guidance provided on the TGA website – Black Triangle Scheme and boxed warning.

Provide **medicine name** in index summary where needed.

Use **high contrast headings** to aid scanning.

Use **appropriate tables** and/or **subheadings** to help group information. *Further guidance is in the template itself.*

Template content (reproduced from image)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

WARNING: [Insert boxed warning, adapted for consumers, if applicable]

[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]

[medicine name]*   2

Full CMI – page 2 (continued)

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

WARNING: [Insert boxed warning, adapted for consumers, if applicable]

[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?
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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]

[medicine name]*   2

Left annotations:

Insert **active ingredient**, **medicine name** and **therapeutic class with explanation**.

Provide **medicine name** and a **plain English explanation** of what the medicine is used to treat (in **indication**).

For example: This medicine is used to treat a lung problem that can cause breathing difficulties and non-stop coughing.

Right annotations:

Consider whether you need to include a subheading for different categories of users, e.g. the elderly, children, infants or people with specific pathological conditions.

Communication principles most relevant for this CMI page.

1 Keep your message clear and to the point

2 Use suitable language for the consumer

3 Use consistent language and messaging

4 Provide information that helps consumers make safe and appropriate decisions

5 Set out information to support findability, understanding and action

Related guidelines in *Writing About Medicines for People*

Refer to **Module 7** for further detail on writing content for this section: *2. What should I know before I use [medicine name]?*

Refer to **Schedule 12** of the regulations for further detail on precautions.

Full CMI – Page 3

Bold key actions and messages for emphasis.

Provide **targeted information** and **step by step guidance**.

Explain **where external links go** in **simple language** so the consumer knows what to expect when they follow it.

Ensure **links are short**, in case consumers need to type in the link manually.

Provide the **most important information first**.

Include information about any **adverse effects** if **stopping treatment** or specific requirements for tapering prior to stopping.

Consider if you need additional **subheading** for interactions with other things such as "**food and drink**" or "**tobacco**".

Communication principles most relevant for this CMI page.

1 Keep your message clear and to the point

2 Use suitable language for the consumer

3 Use consistent language and messaging

4 Provide information that helps consumers make safe and appropriate decisions

5 Set out information to support findability, understanding and action

Related guidelines in *Writing About Medicines for People*

Refer to **Module 7** for further detail on writing content for this section: *2. What should I know before I use [medicine name]?*

Refer to **Schedule 12** of the regulations for further detail on details that could be included in Section 5.

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Separate tables for **less serious** and **serious side effects**.

Sub-headings for side-effects grouped by **how they relate to the body** to make it easier to find a side effect.

For example: Bleeding related, Allergic reaction related.

Explain **side effects** in **plain English**.

For example: "Vomit that looks like coffee grounds", or "crushing chest pain".

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
[Grouping 1 as per effect on body e.g. bleeding-related]: • [list as appropriate] [Grouping 2 as per 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
[Grouping 1 as per effect on body e.g. bleeding-related]: • [list as appropriate] [Grouping 2 as per 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.

[medicine name]*   4

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.

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].

Explain how consumers can access the medicine.

For example: "This medicine is available without a prescription."

Provide a tabulated **list of all active and inactive ingredients** found in the medicine.

Provide **plain English explanation** of 'Active' and 'Inactive' ingredients.

For example: "Active ingredient (ingredients that make the medicine work)"

Describe **what the medicine looks like** in simple language and include the **registration number** for the medicine.

Insert **name of sponsor**, **address, contact details** and insert **month and year** of when document was last reviewed.

Communication principles most relevant for this CMI page.

1 Keep your message clear and to the point

2 Use suitable language for the consumer

3 Use consistent language and messaging

4 Provide information that helps consumers make safe and appropriate decisions

5 Set out information to support findability, understanding and action

Related guidelines in _Writing About Medicines for People_

Refer to **Module 8** for further detail on writing about side effects and reassuring consumers.

Refer to **Schedule 12** of the regulations for further detail on side effects and product details.

List of references

Reference list and further reading

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European Commission,*Guideline on the readability of the labelling and package leaflet of medicinal products for human use; Revision 1, 12 January 2009*. Available online at: https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf.