



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

OTC medicine monograph: Aspirin tablets for oral use

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TGA Health Safety
Regulation

Historical consultation document

DRAFT

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

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Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	OTC Medicines Evaluation /OMA	18/06/13

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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of tablets containing aspirin as a single active ingredient when applied for as an OTC New Product N2 application. Proposed products must comply with all aspects of the monograph relevant to their strength and dosage form to qualify for evaluation as an N2 application.

This monograph should be read in conjunction with the document [Requirements for OTC new product N2 applications](#).

Active substance, dosage forms and strengths

Active substance

This monograph only applies to aspirin (acetylsalicylic acid; CAS No. 50-78-2) and excludes preparations containing any salts and derivatives of aspirin.

Dosage forms and strengths

Acceptable dosage forms and strengths are shown in the table below.

Active substance	Dosage strengths	Dosage forms (excludes sustained release dosage forms)
Aspirin	100 mg	Tablets*
	300 mg	Tablets*
	500 mg	Tablets+

* Chewable, dispersible, effervescent, uncoated and enteric coated tablets only.

+ Chewable, dispersible, effervescent and uncoated tablets only.

Indications

Required therapeutic indications for inclusion in the Australian Register of Therapeutic Goods (ARTG)

Required indications are shown in the table below.

Dosage form and strength	Indications
100 mg tablets	For the treatment of patients with known cardiovascular or cerebrovascular disease, as an antiplatelet agent for prophylaxis against acute myocardial infarction, unstable angina, transient ischaemic attack and cerebrovascular accident (stroke).
300 mg or 500 mg tablets	Temporary relief of pain associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, arthritis, osteoarthritis, rheumatic pain, period pain, fibrositis, neuralgia, sore throat, tennis elbow, and colds and flu. Reduces fever.

Label indications

Acceptable label indications are shown in the table in the table below.

Dosage form & strength	Label indications
100 mg tablets	Reduces the risk of heart attack and stroke in patients with known cardiovascular or cerebrovascular disease by helping to prevent blood clotting.*
300 mg or 500 mg tablets	<p>All or some of the following indications may be included on medicine labels:</p> <ul style="list-style-type: none"> • For the temporary relief of pain and/or inflammation associated with: <ul style="list-style-type: none"> – headache – migraine headache – tension headache – sinus pain – toothache – dental procedures – backache – muscular aches and pains – arthritis – rheumatic pain – menstruation/period pain – fibrositis – neuralgia – sore throat – tennis elbow – symptoms of colds and flu • Reduces fever.

*Permission is required, under Section 42DK of the *Therapeutic Goods Act 1989*, for the use of claims relating to the cardiovascular or cerebrovascular systems on product labelling. Include a request for permission in the application cover letter.

Directions for use

Adults and children 12 years and over*

Dosages must be as shown in the table below.

Dosage Form & Strength	Single Dose	Dose Interval	Maximum Daily Dose
100 mg tablet	1 tablet	One tablet daily	100 mg
300 mg tablet	1-3 tablets	Every 4-6 hours as required	Do not exceed 12 tablets in 24 hours
500 mg tablet	1-2 tablets	Every 4-6 hours as required	Do not exceed 8 tablets in 24 hours

*A higher minimum age can also be specified (eg. Adults 18 years and over for 100 mg tablets).

Enteric coated tablets should include the statement "Swallow whole. Do not crush or chew".

Labelling

Full scale, full colour draft labelling for each proposed pack size must be provided electronically with the application, for assessment of the product's presentation.

Labelling must comply with all relevant Australian requirements, as detailed in the document [Requirements for OTC new product N2 applications](#), including all required warning statements.

Quality requirements

In addition to the requirements outlined in the document *Requirements for OTC New Product N2 applications*, the following specific requirements apply to aspirin monograph products:

Finished product specifications

In addition to other requirements specified in the document [Requirements for OTC new product N2 applications](#), the finished product specifications must comply, at a minimum, with one of the sets of requirements below, as relevant. The requirements below include all relevant BP general monograph requirements and TGO78 requirements. Further reference to these is not required.

Standard uncoated and chewable tablets

The tests and limits in the BP monograph **Aspirin Tablets** with the addition of:

- tablet appearance
- Uniformity of dosage units (BP)
- dissolution (with a limit of $\geq 70\%$ after 45 minutes[†])
- tests and limits for microbiological quality, in compliance with TGO 77.

Dispersible tablets

The tests and limits in the BP monograph **Dispersible Aspirin Tablets** with the addition of:

- tablet appearance
- Uniformity of dosage units (BP)
- disintegration (as per the requirements for dispersible tablets in the BP general monograph **Tablets**)
- fineness of dispersion (as per the requirements for dispersible tablets in the BP general monograph **Tablets**)
- tests and limits for microbiological quality, in compliance with TGO 77.

Effervescent tablets

The tests and limits in the BP monograph **Effervescent Soluble Aspirin Tablets** with the addition of:

- tablet appearance
- Uniformity of dosage units (BP)
- tests and limits for microbiological quality, in compliance with TGO 77.

Enteric coated tablets

The tests and limits in the BP monograph **Gastro-resistant Aspirin Tablets** with the addition of:

- tablet appearance

[†] As specified in the BP's Supplementary Chapter 1E *Dissolution Testing of Solid Oral Dosage Forms*

- Uniformity of dosage units (BP)
- dissolution (with a limit of $\leq 5\%$ after 2 hours in acid and $\geq 70\%$ after 45 minutes+ in phosphate buffer)
- tests and limits for microbiological quality, in compliance with TGO 77.

Container

Aspirin products must be sold in containers that comply with Therapeutic Goods Order No 80, Child Resistant Packaging Requirements for Medicines.

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