



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# OTC medicine monograph: Ibuprofen for oral use

Version 1.1, July 2021

**TGA** Health Safety  
Regulation

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## Contents

<b>Introduction</b>	<b>4</b>
<b>Active substance</b>	<b>4</b>
<b>Dosage forms and strengths</b>	<b>4</b>
<b>Indications</b>	<b>4</b>
Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods	4
Label indications	5
<b>Directions for use</b>	<b>5</b>
Adults and children 7 years and over (solid dose oral preparations)	5
Children 3 months to 12 years (oral liquid suspension)	6
Children 3 months to 12 years (oral liquid suspension)	7
<b>Labelling</b>	<b>9</b>
<b>Quality requirements</b>	<b>9</b>
Active premixes	9
Finished product specifications	9
Coated tablets	9
Orally disintegrating tablets (uncoated)	10
Oral suspensions	10
Container/measuring device	10

## Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral medicines containing ibuprofen as a single active ingredient when applied for as an OTC New Medicine N2 application. Proposed medicines 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 medicine N2 applications](#).

## Active substance

This monograph only applies to medicines containing ibuprofen (CAS no. 15687-27-1) and excludes preparations containing any salts and derivatives of ibuprofen.

## Dosage forms and strengths

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

Active substance	Dosage strengths	Dosage forms (excludes modified release dosage forms)
Ibuprofen	200 mg	Coated tablets
	200 mg	Orally disintegrating tablets
	20 mg/mL (100 mg/5 mL)	Suspension, liquids
	40 mg/mL (200 mg/5 mL)	Suspension, liquids

## Indications

### Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods

Temporary relief of pain and/or inflammation 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.

For paediatric formulations, in addition to any of the indications above that are appropriate to the age group, the following indications would be acceptable: relief of pain associated with teething, earache and/or immunisation.

## Label indications

All or most of the indications listed above should be included as label indications, as appropriate, depending on the intended age group. Label indications must not be restricted to, or emphasise, a single indication or subset of indications (e.g. cold and flu symptoms only, period pain only or headache only). Terms should be exactly as specified above and qualified by the words “temporary relief of pain [and/or inflammation] associated with...”.

## Directions for use

### Adults and children 7 years and over (solid dose oral preparations)

Dosages must be as shown in the table below.

Dosage form and strength	Age	Single dose	Dose interval	Maximum daily dose
200 mg tablet	7 -12 years	1 tablet	Every 6-8 hours when necessary	4 tablets in 24 hours
200 mg tablet	Adults and children 12 years and over	1 - 2 tablets	Every 4-6 hours when necessary	6 tablets in 24 hours

Include the statement *Do not give to children under x years* (where ‘x’ years is the youngest age for which dosage instructions are included on the labels).

## Children 3 months to 12 years (oral liquid suspension)

Dosages for ibuprofen oral liquid suspension in children 3 months to 12 years must be consistent with those shown in the 'Recommended dosages' table below or, alternatively, with those shown in the 'Alternative acceptable dosages' table below.

### Recommended dosages:

Age	Average body weight (kg)	Dose (mg)	Dose (mL) from 20 mg/mL suspension	Dose (mL) from 40 mg/mL suspension
3 – 6 months	6 – 8 kg	40 – 60 mg	2 – 3 mL	1 – 1.5 mL
6 – 12 months	8 – 10 kg	60 – 80 mg	3 – 4 mL	1.5 – 2 mL
1 – 2 years	10 – 12 kg	80 – 100 mg	4 – 5 mL	2 – 2.5 mL
2 – 3 years	12 – 14 kg	100 – 120 mg	5 – 6 mL	2.5 – 3 mL
3 – 4 years	14 – 16 kg	120 – 140 mg	6 – 7 mL	3 – 3.5 mL
4 – 5 years	16 – 18 kg	140 mg	7 mL	3.5 mL
5 – 6 years	18 – 20 kg	140 – 160 mg	7 – 8 mL	3.5 – 4 mL
6 – 7 years	20 – 22 kg	160 – 180 mg	8 – 9 mL	4 – 4.5 mL
7 – 8 years	22 – 25 kg	180 – 200 mg	9 – 10 mL	4.5 – 5 mL
8 – 9 years	25 – 28 kg	200 – 220 mg	10 – 11 mL	5 – 5.5 mL
9 – 10 years	28 – 32 kg	220 – 240 mg	11 – 12 mL	5.5 – 6 mL
10 – 11 years	32 – 36 kg	240 – 280 mg	12 – 14 mL	6 – 7 mL
11 – 12 years	36 – 41 kg	280 – 300 mg	14 – 15 mL	7 – 7.5 mL

**Doses should be given every 6-8 hours as necessary, with no more than four doses in 24 hours.**

Wider age ranges than those listed above could be specified for children aged 1 year and over. Age ranges of "1-3 years" or "2-4 years" would be acceptable, but "1-4 years" or "2-5 years" would not be acceptable. Beyond 3 years of age, age groupings of 2 or 3 years would be acceptable (e.g. 2-4 years, 4-6 years... or 3-6 years, 6-9 years...). Doses must still be consistent with the above table. For children under 12 months, age ranges must be specified as shown in the table.

## Children 3 months to 12 years (oral liquid suspension)

Dosages for ibuprofen oral liquid suspension in children 3 months to 12 years must be consistent with those shown in the 'Recommended dosages' table below or, alternatively, with those shown in the 'Alternative acceptable dosages' table below.

### Recommended dosages:

Age	Average body weight (kg)	Dose (mg)	Dose (mL) from 20 mg/mL suspension	Dose (mL) from 40 mg/mL suspension
3 – 6 months	6 – 8 kg	40 – 60 mg	2 – 3 mL	1 – 1.5 mL
6 – 12 months	8 – 10 kg	60 – 80 mg	3 – 4 mL	1.5 – 2 mL
1 – 2 years	10 – 12 kg	80 – 100 mg	4 – 5 mL	2 – 2.5 mL
2 – 3 years	12 – 14 kg	100 – 120 mg	5 – 6 mL	2.5 – 3 mL
3 – 4 years	14 – 16 kg	120 – 140 mg	6 – 7 mL	3 – 3.5 mL
4 – 5 years	16 – 18 kg	140 mg	7 mL	3.5 mL
5 – 6 years	18 – 20 kg	140 – 160 mg	7 – 8 mL	3.5 – 4 mL
6 – 7 years	20 – 22 kg	160 – 180 mg	8 – 9 mL	4 – 4.5 mL
7 – 8 years	22 – 25 kg	180 – 200 mg	9 – 10 mL	4.5 – 5 mL
8 – 9 years	25 – 28 kg	200 – 220 mg	10 – 11 mL	5 – 5.5 mL
9 – 10 years	28 – 32 kg	220 – 240 mg	11 – 12 mL	5.5 – 6 mL
10 – 11 years	32 – 36 kg	240 – 280 mg	12 – 14 mL	6 – 7 mL
11 – 12 years	36 – 41 kg	280 – 300 mg	14 – 15 mL	7 – 7.5 mL

**Doses should be given every 6-8 hours as necessary, with no more than four doses in 24 hours.**

Wider age ranges than those listed above could be specified for children aged 1 year and over. Age ranges of "1-3 years" or "2-4 years" would be acceptable, but "1-4 years" or "2-5 years" would not be acceptable. Beyond 3 years of age, age groupings of 2 or 3 years would be acceptable (e.g. 2-4 years, 4-6 years... or 3-6 years, 6-9 years...). Doses must still be consistent with the above table. For children under 12 months, age ranges must be specified as shown in the table.

**Alternative acceptable dosages:**

Age	Average body weight (kg)	Dose (mg)	Dose (mL) from 20 mg/mL suspension	Dose (mL) from 40 mg/mL suspension
3 – 6 months	6 – 8 kg	60 – 80 mg	3-4 mL	1.5 – 2.0 mL
6 – 12 months	8 – 10 kg	80 – 100 mg	4-5 mL	2.0 – 2.5 mL
1 – 3 years	10 – 14 kg	100 – 140 mg	5-7 mL	2.5 – 3.5 mL
3 – 5 years	14 – 18 kg	140 – 180 mg	7-9 mL	3.5 – 4.5 mL
5 – 7 years	18 – 22 kg	180 – 220 mg	9 – 11 mL	4.5 – 5.5 mL
7 – 9 years	22 – 28 kg	220 – 280 mg	11 – 14 mL	5.5 – 7.0 mL
9 – 12 years	28 – 40 kg	280 – 400 mg	14 – 20 mL	7.0 – 10 mL

**Doses should be given every 6-8 hours as necessary, up to 3 times a day**

The following points also apply (regardless of which dosage table above is used):

- A medicine label could include only a subset of the age groups – for example, doses only for children aged from 7-12 years.
- Doses must be presented on the labels with ages (in months or years), weights (kg) and volumes (mL). Dosage instructions must also include advice consistent with the following:

*If you know that your child's weight is less than the weight corresponding to their age in the table, choose the dose for their weight.*

- Labels must state the maximum daily dose. For liquid preparations that include doses for more than one age group, this should be stated as: *Do not give more than 4 doses in 24 hours (or 3 doses in 24 hours, depending on the doses specified).*
- Where dosage instructions for infants aged 3-12 months of age are included on the labels, the dosage instructions must include a statement advising that the medicine should only be given to infants aged 3-12 months following medical advice.
- The dosage instructions must include the following statement:  
*Do not give to children [or infants] under x years [or months] (where 'x' years / months is the youngest age for which dosage instructions are included on the labels).*
- A statement to 'Shake the bottle before use' must be included.
- Instructions on how to use a supplied measuring device may be included if necessary. Requirements for measuring devices are included under [Container/measuring device](#).



## Labelling

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

## Quality requirements

In addition to the quality requirements outlined in the document [Requirements for OTC new medicine N2 applications](#), the following specific requirements apply to ibuprofen monograph medicines:

### Active premixes

Where ibuprofen is sourced by the finished product manufacturer as part of an active premix,<sup>1</sup> the finished product manufacturer must, as a minimum, control the premix for appearance/description, identification (one chromatographic and one non-chromatographic test), assay, related substances, residue on ignition or sulfated ash, and heavy metals. The limits applied should be taken from either the BP or USP monograph for ibuprofen (with all limits to be taken from the same monograph), adjusted where necessary to account for the presence of excipients in the mixture (for example, assay). Additional requirements in relation to active premixes are specified in the document [Requirements for OTC new medicine N2 applications](#).

### Finished product specifications

In addition to other requirements specified in the document [Requirements for OTC new medicine N2 applications](#), the finished product specifications must comply, at a minimum, with the relevant set of requirements below.

The requirements below include all relevant BP general monograph/USP General Chapter requirements and TGO78 requirements. Further reference to these is not required. References to pharmacopoeial monographs below refer to the **current** monograph at time of application.

### Coated tablets

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

- tablet appearance
- dissolution (900 mL phosphate buffer pH 7.2, paddle at 50 rpm, 80% (*Q*) after 60 minutes)<sup>2</sup>
- uniformity of dosage units (BP)
- content of 4'-isobutylacetophenone<sup>3</sup> (NMT 0.3% wrt ibuprofen)
- microbiological quality, in compliance with TGO 77.

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<sup>1</sup> For more information on proprietary ingredient mixtures that contain an active ingredient see [Streamlining proprietary ingredient categories](#).

<sup>2</sup> From *Ibuprofen Tablets USP*

<sup>3</sup> Use assay method specified for *Ibuprofen Oral Suspension BP* or *Ibuprofen Tablets USP*, or an alternative equivalent or superior method. The method must be appropriately validated as described in [Requirements for OTC new medicine N2 applications](#).

## Orally disintegrating tablets (uncoated)

The tests and limits in the USP monograph **Ibuprofen Tablets** with the addition of:

- tablet appearance
- tighter limits for ibuprofen content of 92.5-107.5% (in accordance with TGO 78)
- BP/Ph. Eur test and limit (within 3 min) for disintegration, using *water R* at 15-25°C
- test and limits for individual unspecified impurities (0.3%) and total impurities (0.7%)<sup>4</sup>
- microbiological quality, in compliance with TGO 77.

## Oral suspensions

The tests and limits in the BP monograph **Ibuprofen Oral Suspension** with the addition of:

- suspension appearance
- dissolution (900 mL phosphate buffer pH 7.2, paddle at 50 rpm, 80% (*Q*) after 60 minutes)<sup>5</sup>
- content of any preservatives included in the formulation
- suitable test and limits for pH
- suitable test and limits for viscosity
- individual unspecified impurities (0.3%) and total impurities (0.7%)<sup>4</sup>
- microbiological quality, in compliance with TGO 77.

**or**

The tests and limits in the USP monograph **Ibuprofen Oral Suspension** with the addition of:

- suspension appearance
- content of any preservatives included in the formulation
- suitable test and limits for viscosity
- individual unspecified impurities (0.3%) and total impurities (0.7%)<sup>4</sup>
- microbiological quality, in compliance with TGO 77.

## Container/measuring device

- Ibuprofen products must be sold in containers that comply with Therapeutic Goods Order No 80, Child Resistant Packaging Requirements for Medicines.
- If a measuring device is to be supplied with the medicine, calibrations must be exclusively in metric units and must allow all the doses shown on the labels to be measured accurately. Details of the calibrations on the measuring device must be provided with the submission (a sample may also be requested). Further considerations and requirements regarding measuring devices are detailed in [ARGOM Appendix 2: Guidelines on quality aspects of OTC applications, 8. Finished product container](#).

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<sup>4</sup> Use assay method specified for *Ibuprofen Tablets BP* or alternative equivalent or superior methods. Methods must be appropriately validated as described in [Requirements for OTC new medicine N2 applications](#).

<sup>5</sup> From *Ibuprofen Oral Suspension, USP*

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	OTC Medicines Evaluation/OMA	06/09/2013
V1.1	Addition of footnote to information about active premixes	COMB	July 2021

## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605  
<https://www.tga.gov.au>

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