About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, 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 <http://www.tga.gov.au>. 

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# Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
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<tr>
<td>V1.0</td>
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<td>16/12/2014</td>
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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral medicines containing mebendazole 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 medicines N2 applications.

Active substance

This monograph only applies to medicines containing mebendazole (CAS no. 31431-39-7) and excludes any preparations containing any other salts and derivatives of mebendazole.

Dosage forms and strengths

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

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Dosage strength</th>
<th>Dosage forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mebendazole</td>
<td>100 mg</td>
<td>Tablet (chewable and uncoated only)</td>
</tr>
<tr>
<td></td>
<td>20 mg/mL</td>
<td>Oral suspension</td>
</tr>
</tbody>
</table>

Indications

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

Treatment of Enterobius vermicularis (threadworm or pinworm).

For the treatment of other worms such as Ascaris lumbricoides (roundworm), Trichuris trichura (whipworm) and Ancylostoma duodenale and Necator americanus (hookworm) only under medical supervision.

Label indications

- Treatment of threadworm.
- Treatment of roundworm, whipworm and hookworms only on medical advice.

In addition to the above label indications, the following label claim may be included:

- Kills worms.
## Directions for use

Dosages must be as shown in the table below.

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Dosage in adults and children 2 years of age and over</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment of threadworm:</strong></td>
<td></td>
</tr>
<tr>
<td>100 mg tablet</td>
<td>1 tablet to be taken as a single dose.</td>
</tr>
<tr>
<td>20 mg/mL suspension</td>
<td>Give/take 5 mL of suspension as a single dose.</td>
</tr>
<tr>
<td><strong>Treatment of roundworm, hookworm and whipworm:</strong></td>
<td></td>
</tr>
<tr>
<td>100 mg tablet</td>
<td>The recommended dosage for this condition is 1 tablet twice a day for three days.</td>
</tr>
<tr>
<td>20 mg/mL suspension</td>
<td>The recommended dosage for this condition is 5 mL of suspension twice a day for three days.</td>
</tr>
</tbody>
</table>

### Additional instructions

1. The following directions for use must be included:
   - The statements "Do not give to children under 2 years of age" and "It may be taken with or without food".
   - A statement that the tablet may be swallowed whole, chewed (if formulated as a chewable tablet) or crushed.
   - For uncoated and chewable tablets, a statement to the effect that tablets should be crushed before administering to children.
   - For oral suspensions, the direction to shake the bottle well before use.

2. If appropriate and the formulation permits, include advice on the label that the tablets should be crushed and the contents mixed with water, jam or honey before administering to children.

3. The following instructions (or words to the effect of) are required:
   - Threadworms or pinworms are small, very thin worms that look like white threads.
   - Before treating, signs of threadworm should be present.
   - Signs and symptoms of threadworm infestation include:
     - The presence of tiny white threads around the anal region.
- Itching around the anus and vagina, which may result in restless sleep, grinding of teeth and irritability.
  
  - If a household member has threadworms, then each member should be treated at the same time even if they have no symptoms because the worms spread very easily.
  
  - If symptoms persist, see your doctor.

4. To help reduce infection and prevent reinfection, the following measures (or words to the effect of) may be included:
  
  - Keep fingernails short and ensure hands and nails are scrubbed clean.
  
  - Wash hands after using the toilet and before eating.
  
  - Shower rather than bathe for several days after treatment.
  
  - Vacuum carpet and wash floors, clothing and linen in hot water.
  
  - If reinfection occurs, repeat treatment 2-4 weeks after initial dose.

Labels

Labelling must comply with all relevant Australian requirements, as detailed in the document Requirements for OTC new medicines N2 applications, including all required warning statements.

Advisory statement

The following statement is required:

If you are pregnant or may become pregnant, check with your doctor or pharmacist before taking this medicine.*

#This statement will be revised pending a final outcome of a RASML consultation on a pregnancy and breastfeeding warning statement for mebendazole.

Quality requirements

In addition to the quality requirements outlined in the document Requirements for OTC new medicines N2 applications, the following specific requirements apply to mebendazole monograph medicine:

Finished product specifications

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

The requirements below include all relevant USP General Chapter requirements and TGO 78 requirements. Further reference to these is not required. References to the pharmacopoeial monographs below refer to the current monographs at the time of application.
Mebendazole tablet
The tests and limits in the USP monograph *Mebendazole Tablets* with the addition of:

- tablet appearance;
- content of mebendazole (NLT 92.5% and NMT 107.5%)\(^1\) in compliance with TGO 78;
- individual unspecified impurities (NMT 0.5%); and total impurities (NMT 1.0%), and
- microbiological quality in compliance with TGO 77.

Mebendazole oral suspension
The tests and limits in the USP monograph *Mebendazole Oral Suspension* with the addition of:

- solution appearance;
- individual unspecified impurities (NMT 0.5%); and total impurities (NMT 1.0%);
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

\(^1\) in place of the Mebendazole Tablets USP requirement of NLT 90.0% and NMT 110.0%