



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	300620	Laxatone
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Global Therapeutics Pty Ltd	
<b>Postal Address</b>	PO Box 1999, BYRON BAY, NSW, 2481 Australia	
<b>ARTG Start Date</b>	9/03/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

**Conditions**

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

**Products**

**1 . Laxatone**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/01/2019
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

- [01] Traditionally used in Chinese Medicine to relieve constipation (associated with dry stools and sluggish bowel function).
- [02] Traditionally used in Chinese Medicine to provide a laxative and purgative action and moistens and lubricates the intestines
- [03] Traditionally used in Chinese Medicine to increase peristalsis, to reduce transit time and promote bowel movements (evacuation of the large intestine/colon)
- [04] In Traditional Chinese Medicine terms, this medicine has a downward-directing action, clearing accumulations associated with constipation, to support normal bowel movements.
- [05] According to Traditional Chinese Medicine philosophy, this formula contains herbs that cools and moistens to drain excess heat and lubricate the intestines, as well as tonifies blood.
- [06] Recognised in traditional Chinese Medicine to provide digestant (digestive) actions to stimulate digestion
- [07] Recognised in Traditional Chinese Medicine as a cholagogue, to promote bile flow.
- [08] Contains Rheum (Rhubarb) which clears heat in the stomach and intestines and stimulates downward movement of Qi to move the bowels, a primary strategy for relieving constipation in Traditional Chinese Medicine.
- [09] Dong quai is used in Traditional Chinese Medicine to nourish (tonify) and move (invigorate) blood, moisten the intestines and unblock the bowels (when intestines are dry due to blood deficiency).
- [10] Bitter orange is used to regulate the Qi, and is commonly used for constipation. It directs Qi downwards and unblocks the bowels

**Warnings**

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Drink plenty of water (or words to that effect).

Use in children under 12 years is not recommended.

Prolonged use may cause serious bowel problems.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Angelica polymorpha</b>	<b>57.14 mg</b>
Equivalent: Angelica polymorpha	400 mg
<b>Citrus aurantium</b>	<b>16 mg</b>
<b>Glycyrrhiza uralensis</b>	<b>50 mg</b>
Equivalent: Glycyrrhiza uralensis	250 mg
<b>Rehmannia glutinosa</b>	<b>83.34 mg</b>
Equivalent: Rehmannia glutinosa	500 mg
<b>Rheum officinale</b>	<b>75 mg</b>
Equivalent: Rheum officinale	750 mg
Equivalent: Hydroxyanthracene derivatives calculated as rhein	7.5 mg
<b>Trichosanthes kirilowii</b>	<b>83.34 mg</b>
Equivalent: Trichosanthes kirilowii	500 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
hypromellose  
macrogol 400  
magnesium stearate  
microcrystalline cellulose

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