



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	383716	MediHerb Willow Bark
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	9/02/2022	
Product Category	Medicine	
Status	Active	
Approval Area	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.

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 . MediHerb Willow Bark

Product Type	Single Medicine Product	Effective Date	15/02/2022
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Permitted Indications

- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Analgesic/Anodyne/relieve pain
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Indication Requirements

- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Product presentation must only refer to mild rheumatic aches/pains.
- Label statement: If symptoms persist, talk to your health professional.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must only refer to mild joint symptoms.
- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
- Label statement: Not to be used in children under 5 years.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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If symptoms persist, seek the advice of a healthcare professional.
Not recommended for use during pregnancy or lactation
Do not use while breastfeeding.
For practitioner dispensing only.
Do not use if pregnant or likely to become pregnant (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

Salix purpurea stem bark Extract dry concentrate standardised **400 mg**
Equivalent: Salix purpurea (Dry) 8 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
croscarmellose sodium
hypromellose
magnesium stearate
microcrystalline cellulose
silicon dioxide

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