

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 345845 Oriental Botanicals Tienchi Ginseng

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 13/10/2020
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 . Oriental Botanicals Tienchi Ginseng

Product Type Single Medicine Product Effective Date 1/12/2020

Permitted Indications

Traditionally used in Chinese medicine to invigorate/activate Blood

Traditionally used in Chinese medicine to promote flow of Blood

Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis

Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation

Traditionally used in Chinese medicine to analgesic/Anodyne/relieve pain

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of soft tissue trauma

Traditionally used in Chinese medicine to helps enhance/promote healthy blood circulation

Traditionally used in Chinese medicine to helps reduce/decrease/relieve mild nose bleeds

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of muscle injury/ailments

Traditionally used in Chinese medicine to aid/assist/helps in the management of muscle sprain/strain

Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of muscle sprain/strain

Linked indication - Anti-inflammatory/relieve inflammation

Linked indication - Analgesic/Anodyne/relieve pain

Traditionally used in Chinese medicine to decrease/reduce heavy menstruation/periods

Traditionally used in Chinese medicine to decrease/reduce/relieve bruise pain

Traditionally used in Chinese medicine to decrease/reduce/relieve bruise swelling

Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)

Traditionally used in Chinese medicine to enhance/improve healing of minor skin wound/cuts/scratches/abrasions

Traditionally used in Chinese medicine to maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to mild nose bleed.

Standard Indications

No Standard Indications included on Record

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This is not an ARTG Certificate document.



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Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Cinnamomum camphora twig leafy Extract dry concentrate

Equivalent: Cinnamomum camphora (Dry)

Panax notoginseng root Extract dry concentrate

Equivalent: Panax notoginseng (Dry)

Other Ingredients (Excipients)

betadex

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

silicon dioxide

50 mg

750 mg

500 mg

1.5 g

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