



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	344737 Oriental Botanicals Pain & Inflammation
ARTG entry for	Medicine Listed
Sponsor	McPherson's Consumer Products Pty Ltd
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia
ARTG Start Date	28/09/2020
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 Pain & Inflammation

Product Type	Single Medicine Product	Effective Date	23/08/2021
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Permitted Indications

Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
Anti-inflammatory/relieve inflammation
Analgesic/Anodyne/relieve pain
Traditionally used in Chinese medicine to analgesic/Anodyne/relieve pain
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild rheumatic aches and pains
Traditionally used in Chinese 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 helps reduce the occasional occurrence of symptoms of gout
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint inflammation/swelling
Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint inflammation/swelling
Traditionally used in Chinese medicine to decrease/reduce/relieve mild joint pain/soreness
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild joint pain/soreness
Traditionally used in Chinese medicine to antispasmodic/spasmolytic
Traditionally used in Chinese medicine to helps decrease/reduce/relieve mild muscle spasms/twitches
Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness
Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle pain/ache/soreness
Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
Traditionally used in Chinese medicine to decrease/reduce/relieve mild migraine symptoms

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to mild rheumatic aches/pains.
Product presentation must only refer to mild joint symptoms.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Product presentation must only refer to mild migraine.

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Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica pubescens root Extract dry concentrate	55 mg
Equivalent: Angelica pubescens (Dry)	275 mg
Atractylodes macrocephala root Extract dry concentrate	20 mg
Equivalent: Atractylodes macrocephala (Dry)	100 mg
Boswellia serrata gum oleoresin Extract dry concentrate	228 mg
Equivalent: Boswellia serrata (Dry)	912 mg
Eleutherococcus nodiflorus root bark Extract dry concentrate	100 mg
Equivalent: Eleutherococcus nodiflorus (Dry)	400 mg
Eucommia ulmoides stem bark Extract dry concentrate	66.67 mg
Equivalent: Eucommia ulmoides (Dry)	400 mg
Gentiana macrophylla root Extract dry concentrate	75 mg
Equivalent: Gentiana macrophylla (Dry)	300 mg
Salix alba stem bark Extract dry concentrate	200 mg
Equivalent: Salix alba (Dry)	1.2 g
Saposhnikovia divaricata root Extract dry concentrate	187.5 mg
Equivalent: Saposhnikovia divaricata (Dry)	750 mg

Other Ingredients (Excipients)

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

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