



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	312611	METAGENICS INFLAVONOID SUSTAINED CARE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	17/12/2018	
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 . METAGENICS INFLAVONOID SUSTAINED CARE

Product Type	Single Medicine Product	Effective Date	10/12/2020
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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
- Decrease/reduce/relieve mild joint aches and pains
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Linked indication - Decrease/reduce/relieve mild joint stiffness
- Decrease/reduce/relieve mild joint inflammation/swelling
- Traditionally used in Western herbal medicine to decrease/reduce/relieve muscle pain/ache/soreness

Indication Requirements

- 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.
- Product presentation must only refer to mild joint symptoms.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Boswellia serrata gum oleoresin Extract dry concentrate	150 mg
Equivalent: Boswellia serrata (Dry)	1.5 g
Curcuma longa rhizome Extract dry concentrate	167 mg
Equivalent: Curcuma longa (Dry)	4.17 g
Harpagophytum procumbens root Extract dry concentrate	38.52 mg
Equivalent: Harpagophytum procumbens (Dry)	866.7 mg
Piscidia piscipula stem bark Extract dry concentrate	62.5 mg
Equivalent: Piscidia piscipula (Dry)	250 mg

Other Ingredients (Excipients)

calcium phosphate
chlorophyllin-copper complex
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potassium acetate
purified water
sorbitan monolaurate

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