



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

## Public Summary

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

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

Linked indication - Decrease/reduce/relieve mild joint stiffness

Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

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

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

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