

# **Australian Government**

### **Department of Health**

# Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 342333 Eagle Joint Ease

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 26/08/2020
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 . Eagle Joint Ease

Product Type Single Medicine Product Effective Date 5/11/2021

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Helps decrease/reduce/relieve cartilage loss/wear/tear/damage

Decrease/reduce/relieve mild joint aches and pains in elderly individuals

Decrease/reduce/relieve mild joint aches and pains

Decrease/reduce/relieve mild rheumatic aches and pains

Decrease/reduce/relieve mild rheumatic aches and pains in elderly individuals

Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis in elderly individuals

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 pain/soreness Linked indication - Decrease/reduce/relieve mild joint aches and pains

Linked indication - Decrease/reduce/relieve mild rheumatic aches and pains

Linked indication - Decrease/reduce/relieve mild joint stiffness

Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling

Helps maintain/supports healthy joint cartilage growth/development/production

Helps maintain/support joint cartilage health

Helps enhance/promote healthy joint function in elderly individuals

Helps enhance/promote healthy joint function

Helps enhance/promote joint health in elderly individuals

Helps enhance/promote joint health

Maintain/support joint health

Decrease/reduce/relieve mild joint inflammation/swelling

Decrease/reduce/relieve mild joint inflammation/swelling in elderly individuals

Maintain/support joint mobility/flexibility in elderly individuals

Maintain/support joint mobility/flexibility

Helps enhance/improve/promote joint mobility in elderly individuals

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Helps enhance/improve/promote joint mobility

Decrease/reduce/relieve mild joint pain/soreness in elderly individuals

Decrease/reduce/relieve mild joint pain/soreness

Decrease/reduce/relieve mild joint stiffness in elderly individuals

Decrease/reduce/relieve mild joint stiffness

### **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.

Product presentation must only refer to mild rheumatic aches/pains.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

#### **Standard Indications**

No Standard Indications included on Record

#### **Specific Indications**

No Specific Indications included on Record

#### Warnings

For practitioner dispensing only.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet. Derived from seafood.

Contains crustacea OR Contains crustacean products.

Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.

If symptoms persist, seek the advice of a healthcare professional.

### **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**

Boswellia serrata gum Extract dry concentrate	57.14 mg
Equivalent: Boswellia serrata (Dry)	400 mg
colecalciferol	.0025 mg
Curcuma longa rhizome Extract dry concentrate	4 mg
Equivalent: Curcuma longa (Dry)	100 mg
glucosamine sulfate potassium chloride	663 mg
Equivalent: glucosamine sulfate	500 mg
Equivalent: potassium chloride	163 mg
lecithin	100 mg
magnesium orotate dihydrate	103.58 mg
Equivalent: magnesium	6.65 mg
manganese amino acid chelate	25 mg
Equivalent: manganese	5 mg
nicotinamide	200 mg
Silybum marianum seed Extract dry concentrate	5 mg

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Equivalent: Silybum marianum (Dry)

sodium ascorbate

Equivalent: ascorbic acid

Vitis vinifera seed Extract dry concentrate

Equivalent: Vitis vinifera (Dry)

120 mg

### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

croscarmellose sodium

dl-alpha-tocopherol

hydrogenated soya oil

hydrolysed gelatin

hypromellose

magnesium stearate

maize starch

microcrystalline cellulose

povidone

silicon dioxide

sucrose

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