Public Summary

Summary for ARTG Entry:	199296 METAGENICS ARTHREX
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	11/07/2012
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 ARTHREX

Product Type Single Medicine Product **Effective Date** 19/05/2020

Permitted Indications

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Maintain/support bone strength

Help maintain/support bone mineralisation

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

Linked indication - Maintain/support joint mobility/flexibility
Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling
Linked indication - Decrease/reduce/relieve mild joint pain/soreness

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

Helps maintain/support joint cartilage health

Maintain/support joint health

Decrease/reduce/relieve mild joint pain/soreness in athletes

Maintain/support muscle strength in elderly individuals

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.

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

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

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

Not to be taken by children under 2 years old (or words to that effect).

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.

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

borax	**1.76 mg/g**
Equivalent: boron	200 microgram/g
colecalciferol	**1.6666 microgram/g**
colloidal anhydrous silica	**2.67 mg/g**
dimethyl sulfone	**100 mg/g**
Gelatin	**666.67 mg/g**
glucosamine sulfate potassium chloride	**133.33 mg/g**
Equivalent: glucosamine sulfate	100 mg/g
Equivalent: potassium chloride	32.8 mg/g
phytomenadione	**4.67 microgram/g**

Other Ingredients (Excipients)

Acacia
cocoa powder
dl-alpha-tocopherol
Flavour
maize starch
maltodextrin
medium chain triglycerides
potassium bicarbonate
silicon dioxide
Steviol glycosides
sucrose

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