



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	292905	Mediherb Joint Defence
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	17/08/2017	
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 . Mediherb Joint Defence

Product Type	Single Medicine Product	Effective Date	19/02/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support general health and wellbeing
- Helps decrease/reduce/relieve cartilage loss/wear/tear/damage
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support (state mineral) absorption in bones
- Help maintain/support bone mineralisation
- Decrease/reduce/relieve mild joint aches and pains
- Decrease/reduce/relieve mild rheumatic aches and pains
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis in aging individuals
 - 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 pain/soreness
 - Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
 - 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 inflammation/swelling
 - Linked indication - Decrease/reduce/relieve mild joint pain/soreness
 - Linked indication - Decrease/reduce/relieve mild joint stiffness
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps maintain/supports healthy joint cartilage growth/development/production
- Helps maintain/support joint cartilage health
- Helps enhance/promote healthy joint function in aging individuals
- Helps enhance/promote healthy joint function
- Maintain/support joint health
- Maintain/support joint health in aging individuals
- Decrease/reduce/relieve mild joint inflammation/swelling
- Maintain/support joint mobility/flexibility
- Maintain/support joint mobility/flexibility in aging individuals

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Helps enhance/improve/promote joint mobility in aging individuals
Helps enhance/improve/promote joint mobility
Decrease/reduce/relieve mild joint pain/soreness
Decrease/reduce/relieve mild joint stiffness
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

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. 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 not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
Label statement: If symptoms persist, talk to your health professional.
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must only refer to mild rheumatic aches/pains.
Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
Contains Fish/fish products.
For practitioner dispensing only.
Adults 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.
Contains crustacean/crustacean products.
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

borax	6.29 mg
Equivalent: boron	712.5 microgram
Boswellia serrata gum oleoresin Extract dry concentrate	104 mg
Equivalent: Boswellia serrata (Dry)	728 mg
bovine sodium chondroitin sulfate	330 mg
Equivalent: chondroitin sulfate	300 mg

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

colecalfiferol	.0062 mg
glucosamine sulfate potassium chloride	498 mg
Equivalent: potassium chloride	60.7 mg
Equivalent: glucosamine sulfate	375 mg
manganese amino acid chelate	18.8 mg
Equivalent: manganese	3.75 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
crospovidone
dl-alpha-tocopherol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
hypromellose
magnesium stearate
maize starch
microcrystalline cellulose
povidone
silicon dioxide
sucrose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary