



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	122467	COLLAGENICS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	6/10/2005	
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 . COLLAGENICS

Product Type	Single Medicine Product	Effective Date	5/03/2020
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Permitted Indications

- Maintain/support collagen health
- Maintain/support connective tissue health
- Helps enhance/promote connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Helps maintain/support joint cartilage health
- Helps enhance/promote healthy joint function
- Maintain/support joint health
- Maintain/support muscle health
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
 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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 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

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Warnings

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

If symptoms persist consult your healthcare practitioner (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.

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

ascorbic acid	50 mg
borax	8.8 mg
Equivalent: boron	1 mg
colecalfiferol	.0035 mg
Equisetum arvense herb Extract dry concentrate	181.82 mg
Equivalent: Equisetum arvense (Dry)	1 g
ferrous fumarate	15.2 mg
Equivalent: iron	5 mg
lysine hydrochloride	135 mg
magnesium citrate	625 mg
Equivalent: magnesium	100 mg
manganese sulfate monohydrate	15.4 mg
Equivalent: manganese	5 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.23 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
carrageenan
croscarmellose sodium
dl-alpha-tocopherol
hypromellose
macrogol 8000
maize starch
medium chain triglycerides
microcrystalline cellulose
powdered cellulose
silicon dioxide
sodium starch glycollate
stearic acid
sucrose

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