

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 344470 METAGENICS BIOFLAVONOIDS PLUS C

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 25/09/2020
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.

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 BIOFLAVONOIDS PLUS C

 Product Type
 Single Medicine Product
 Effective Date
 25/09/2020

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support collagen formation

Maintain/support healthy teeth

Maintain/support connective tissue health

Maintain/support bone health

Decrease/reduce/relieve symptoms of hayfever

Helps decrease/reduce/relieve symptoms of mild allergies

Maintain/support healthy immune system function

Decrease/reduce/relieve common cold duration

Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Decrease/reduce/relieve the severity of common cold symptoms

Relieve symptoms of mild upper respiratory tract infections

Maintain/support skin health

Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)

Maintain/support skin repair/healing/regeneration

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Product presentation must not imply or refer to serious immunological diseases.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

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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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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 500 mg
Citrus bioflavonoids extract 83.33 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

glycerol

hypromellose

magnesium stearate

microcrystalline cellulose

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