



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	344470	METAGENICS BIOFLAVONOIDS PLUS C
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	25/09/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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.

Public Summary

