Public Summary

Summary for ARTG Entry:	342059 METAGENICS ULTRA FLORA IMMUNE CONTROL
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	24/08/2020
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 ULTRA FLORA IMMUNE CONTROL

Product Type Single Medicine Product **Effective Date** 24/08/2020

Permitted Indications

Maintain/support intestinal good/beneficial/friendly flora in adolescents

Maintain/support intestinal good/beneficial/friendly flora

Decrease/reduce/relieve symptoms of hayfever in adolescents

Decrease/reduce/relieve symptoms of hayfever

Helps decrease/reduce/relieve symptoms of mild allergies
- Linked indication - Anti-inflammatory/relieve inflammation
- Linked indication - Helps enhance/improve/promote immune system function

Helps decrease/reduce/relieve symptoms of mild allergies in adolescents
- Linked indication - Anti-inflammatory/relieve inflammation
- Linked indication - Helps enhance/improve/promote immune system function

Helps decrease/reduce/relieve symptoms of mild allergies in adolescents

Helps decrease/reduce/relieve symptoms of mild allergies

Decrease/reduce/relieve symptoms of allergic rhinitis in adolescents

Decrease/reduce/relieve symptoms of allergic rhinitis

Helps decrease/reduce/relieve symptoms of seasonal allergies

Helps decrease/reduce/relieve symptoms of seasonal allergies in adolescents

Helps reduce occurrence of symptoms of mild allergies in adolescents

Helps reduce occurrence of symptoms of mild allergies

Maintain/support immune system health

Maintain/support immune system health in adolescents

Maintain/support healthy immune system function

Maintain/support healthy immune system function in adolescents

Indication Requirements

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

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

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

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Lactobacillus paracasei	**5 billion CFU**
Lactobacillus rhamnosus	**20 billion CFU**

Other Ingredients (Excipients)

disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
potable water
potassium acetate
sodium ascorbate
sucrose