Public Summary

Summary for ARTG Entry:	290545 METAGENICS ULTRA FLORA MOTHER AND BABY
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	22/06/2017
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.

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 MOTHER AND BABY

Product Type Single Medicine Product **Effective Date** 8/09/2020

Permitted Indications

Maintain/support general health and wellbeing in breastfeeding women
Maintain/support general health and wellbeing in healthy infants
Maintain/support general health and wellbeing in post-partum women
Maintain/support intestinal good/beneficial/friendly flora in breastfeeding women
Maintain/support intestinal good/beneficial/friendly flora in healthy infants
Maintain/support intestinal good/beneficial/friendly flora in post-partum women
Maintain/support immune system health in healthy infants
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health

Indication Requirements

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Bifidobacterium animalis ssp lactis	**5 billion CFU**
Bifidobacterium breve	**5 billion CFU**
Bifidobacterium longum	**5 billion CFU**
Lactobacillus rhamnosus	**10 billion CFU**

Other Ingredients (Excipients)

calcium phosphate
disodium edetate
gellan gum
glucose
hypromellose
magnesium stearate
maltodextrin
potable water
potassium acetate
silicon dioxide
sodium ascorbate
sucrose