Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	383796	UltraBiotic MumCare

ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia
ARTG Start Date	10/02/2022
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.

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 . UltraBiotic MumCare

Product Type	Single Medicine Product	**Effective Date**	10/02/2022

Permitted Indications

Maintain/support bone health

Maintain/support intestinal health

Maintain/support intestinal good/beneficial/friendly flora

Maintain/support healthy immune system function

Maintain/support maternal health

Indication Requirements

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 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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Public Summary

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Bifidobacterium animalis ssp lactis	**2.375 billion CFU**
Bifidobacterium bifidum	**.125 billion CFU**
colecalciferol	**.0055 mg**
Lactobacillus paracasei	**1.25 billion CFU**
Lactobacillus salivarius ssp salivarius	**6.25 billion CFU**

Other Ingredients (Excipients)

Acacia
colloidal anhydrous silica
dibasic potassium phosphate
disodium edetate
dl-alpha-tocopherol
gellan gum
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
monobasic potassium phosphate
potable water
potassium acetate
silicon dioxide
sodium ascorbate
sodium chloride
sucrose
trehalose dihydrate

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