



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	269733	UB ZonuGuard
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	11/02/2016	
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 . UB ZonuGuard

Product Type	Single Medicine Product	Effective Date	4/09/2020
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support taste sensation
Decrease/reduce/relieve bowel discomfort
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Maintain/support healthy mucous linings of the digestive system
Aid/assist digestion of lactose
Maintain/support digestive system health
Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa
Maintain/support intestinal good/beneficial/friendly flora
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
Help restore good/beneficial/friendly gut flora after antibiotic use
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Maintain/support gastrointestinal system health
Maintain/support gastrointestinal mucosal membrane health
Decrease/reduce/relieve abdominal bloating/distention
Relieve digestive discomfort
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium longum	5 billion CFU
Lactobacillus acidophilus	5 billion CFU
Lactobacillus plantarum	50 billion CFU
Lactobacillus rhamnosus	50 million CFU
zinc amino acid chelate	22.1 mg
Equivalent: zinc	4.42 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary