



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	209354	INNER HEALTH CANDEX SB
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	10/05/2013	
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 . INNER HEALTH CANDEX SB

Product Type	Single Medicine Product	Effective Date	24/06/2020
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Permitted Indications

Maintain/support general health and wellbeing
Maintain/support healthy digestive system function in children over 12 years of age
Maintain/support healthy digestive system function
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support intestinal good/beneficial/friendly flora in children over 12 years of age
Maintain/support gastrointestinal system health in children over 12 years of age
Maintain/support gastrointestinal system health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support vaginal healthy flora/microflora

Indication Requirements

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

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



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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 acidophilus	32 billion organisms
Lactobacillus rhamnosus	4 billion organisms
Saccharomyces cerevisiae (Boulardii)	4 billion organisms
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
colloidal anhydrous silica	
disodium edetate	
gellan gum	
hypromellose	
magnesium stearate	
maltodextrin	
microcrystalline cellulose	
potable water	
potassium acetate	
sodium ascorbate	
sorbitan monostearate	
sucrose	

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