



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	147178	4LifeTransfer Factor Classic
ARTG entry for	Medicine Listed	
Sponsor	4 Life Research Pty Ltd	
Postal Address	Unit 1 Building C 46 Brookhollow Avenue, BAULKHAM HILLS, NSW, 2153 Australia	
ARTG Start Date	10/11/2007	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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. 4LifeTransfer Factor Classic

Product Type	Single Medicine Product	Effective date	10/11/2007
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Aids, assists or helps in the maintenance of general well-being

Specific Indications

Colostrum contains specialised proteins that support the immune function including immunoglobulins, especially IgG1, lactoferrin, and lactoperoxidase. IgG is a key immune-supporting component found in colostrum. Colostrum includes a broad-spectrum of antibodies lysozyme, growth factors, and cytokines. The immune components present in colostrum are well recognised for the proper function of the human immune system. Colostrum contains the same immune factors found in human breast milk. including: immunoglobulins, oligosaccharides, growth factors, lactoperoxidase, lactoferrin, bioactive peptides, nucleosides, lysozyme, and cytokines. Immunoglobulins, are specific immune proteins that are produced by the body in response to exposure to an antigen. An antigen is a foreign substance that enters the body, typically by ingestion, inhalation, or skin abrasions. Antigens cause an immune response when recognised by the immune system.

Warnings

Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.

Additional Product information

Pack Size/Poison information

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Pack Size	Poison Schedule
Components	
1. Medicine Component	
Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	
Active Ingredients	
bovine colostrum powder	334.18 mg

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