



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370399	Berb-Evail
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	30/06/2021	
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 . Berb-Evail

Product Type	Single Medicine Product	Effective Date	21/07/2023
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Anti-inflammatory/relieve inflammation
Helps in the maintenance of healthy blood lipids/blood fats
Helps maintain/support healthy cholesterol
Helps maintain/support healthy blood sugar/glucose
Maintain/support cardiovascular system health
Maintain/support intestinal health
Maintain/support intestinal transit time
Maintain/support gastrointestinal system health
Maintain/support healthy liver function
Maintain/support liver health
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism

Indication Requirements

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range
Product presentation must not imply or refer to serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Specific Indications

No Specific Indications included on Record

Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
-----------	-----------------

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Berberis aristata root Extract dry concentrate	500 mg
---	---------------

Equivalent: Berberis aristata (Dry)	2.5 g
-------------------------------------	-------

Other Ingredients (Excipients)

annatto

Bixa orellana

Gelatin

glycerol

medium chain triglycerides

purified water

Quillaia Powder

© 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