



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	298971	Equazen
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
ARTG Start Date	25/01/2018	
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 . Equazen

Product Type	Single Medicine Product	Effective Date	25/01/2018
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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 or improvement of general well-being.

Specific Indications

- [1] Helps to improve concentration/attention and language development [learning and reading]
- [2] Assists in maintaining and developing aspects of brain and eye function
- [3] Helps the development of the eye and brain: specifically vision, learning ability, and concentration
- [4] Helps assist visual fatigue and eyestrain
- [5] May support working memory/memory concentration, learning and reading
- [6] May support improved memory & concentration problems in children with low essential fatty acids in the diet
- [7] May play a central role in healthy neuronal function
- [8] May help to maintain mental and cognitive function/health as you age
- [9] Supports attention and improves reading ability in mainstream school children
- [10] Equabalance 9:3:1 provides a unique ratio of fatty acids. Essential fatty acids (EPA & DHA) along with GLA are involved in a shift towards the production of predominately anti-inflammatory eicosanoids. Essential fatty acids are required for the structure of cell membranes and cell to cell communication.
- [11] Research has demonstrated EPA to modulate the activity of the enzyme PLA2. The activity of PLA2 coupled with membrane fatty acid composition may play a central role in healthy neuronal function.

Warnings



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Keep out of reach of children (or words to that effect).

If symptoms persist consult your healthcare practitioner (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

Evening Primrose Oil	100 mg
Equivalent: gamma-linolenic acid	10 mg
Fish oil - rich in Omega-3 acids	400 mg
Equivalent: docosahexaenoic acid	29 mg
Equivalent: eicosapentaenoic acid	93 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

Gelatin

glycerol

purified water

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