



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370174	Equazen Chews
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	Level 2 / 170 Pacific Highway, St. Leonards, NSW, 2065 Australia	
ARTG Start Date	24/06/2021	
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 . Equazen Chews

Product Type	Single Medicine Product	Effective Date	24/06/2021
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Permitted Indications

- Maintain/support healthy eye function in children
- Maintain/support healthy eye function
- Maintain/support eye health
- Helps maintain/support healthy vision development in children
- Maintain/support general health and wellbeing
- Helps enhance/improve/promote/increase attention span in children
- Maintain/support cognitive development in children
- Maintain/support mental concentration/focus/clarity in children
- Enhance/improve/promote/increase cognitive performance in children
- Maintain/support cognitive function/mental function in children
- Maintain/support cognitive function/mental function
- Maintain/support learning and information processing in children
- Enhance/improve/promote learning ability/function in children
- Maintain/support memory/mental recall in children
- Maintain/support brain function
- Maintain/support brain function in children
- Maintain/support brain/central nervous system development in children

Indication Requirements

- Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to neurological conditions or developmental delays.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

No Warnings included on Record

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

concentrated fish Omega-3 triglycerides 155 mg

Evening Primrose Oil 100 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

Flavour

Gelatin

glycerol

maize starch

microcrystalline cellulose

purified water

Soya Oil

xylitol

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