



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	377285	Equazen Forte Capsules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SFI Australasia	
<b>Postal Address</b>	Level 2 / 170 Pacific Highway, St. Leonards, NSW, 2065 Australia	
<b>ARTG Start Date</b>	2/11/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 Forte Capsules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/11/2021
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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  
Maintain/support cognitive function/mental function in children  
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 mental illnesses, disorders or conditions.  
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 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, enteric

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

concentrated fish Omega-3 triglycerides 465 mg

Evening Primrose Oil 300 mg

**Other Ingredients (Excipients)**

d-alpha-tocopherol

ethylcellulose

Gelatin

glycerol

medium chain triglycerides

oleic acid

purified water

sodium alginate

Soya Oil

stearic acid

strong ammonia solution

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