



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|---------------------------|
| Summary for ARTG Entry: | 218217 | Blackmores Vitamin A 5000 |
| ARTG entry for | Medicine Listed | |
| Sponsor | Blackmores Ltd | |
| Postal Address | PO Box 1725, WARRIEWOOD, NSW, 2102 Australia | |
| ARTG Start Date | 6/12/2013 | |
| 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.

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 . Blackmores Vitamin A 5000

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 18/05/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Maintain/support healthy eye function
Aids/assists eye adaption to variations in light intensity/night vision
Maintain/support healthy eyesight/vision
Maintain/support body mucous membrane health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support skin health

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 serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--------------------------|-------------------|
| retinol palmitate | 2.75 mg |
| Equivalent: vitamin A | 1500 RE/microgram |

Other Ingredients (Excipients)

dl-alpha-tocopherol

Gelatin

glycerol

iron oxide black

iron oxide red

mixed (low-alpha type) tocopherols concentrate

purified water

Soya Oil

© 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