## **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 384900 Henry Blooms VitaQIK Liposomal D3 & K2

ARTG entry for Medicine Listed

**Sponsor** Phytologic Holdings Pty Limited

Postal Address 16-20 Baker Street, Banksmeadow, NSW, 2019

Australia

ARTG Start Date 1/03/2022
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 . Henry Blooms VitaQIK Liposomal D3 & K2

Product Type Single Medicine Product Effective Date 18/03/2022

## Permitted Indications

Maintain/support general health and wellbeing

Maintain/support bone health

Maintain/support bone strength

Help maintain/support bone mineralisation

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Maintain/support joint health

Maintain/support healthy cardiovascular system function

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals

## **Indication Requirements**

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

## Page 1 of 2



# **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

Product presentation must not imply or refer to serious cardiovascular conditions.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

#### Standard Indications

No Standard Indications included on Record

## **Specific Indications**

No Specific Indications included on Record

#### Warnings

Contains ethanol or contains alcohol.

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Adults only.

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

Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.

### **Additional Product information**

## Pack Size/Poison information

Pack Size Poison Schedule

### Components

1 . Formulation 1

Dosage FormOral LiquidRoute of AdministrationOral

Visual Identification

**Active Ingredients** 

colecalciferol .0125 mg/mL menaquinone 7 5 microgram/mL

## Other Ingredients (Excipients)

Acacia

citric acid

d-alpha-tocopherol

ethanol

Flavour

fractionated coconut oil

glycerol

lecithin

Lemon Oil

liquid glucose

menthol

potassium sorbate

purified water

silicon dioxide

sodium ascorbate

sodium benzoate

thaumatin

tocofersolan

© 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.