Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	393591 My Liposomal D+K
ARTG entry for	Medicine Listed
Sponsor	Thera Health Pty Ltd
Postal Address	18/93 Rivergate Place, Murarrie, QLD, 4172 Australia
ARTG Start Date	8/08/2022
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 . My Liposomal D+K

Product Type Single Medicine Product **Effective Date** 8/08/2022

Permitted Indications

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Maintain/support bone health

Maintain/support bone strength

Help maintain/support bone mineralisation

Maintain/support cardiovascular system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Maintain/support (state vitamin/mineral) within normal range

Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

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: If symptoms persist, talk to your health professional.

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 cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

colecalciferol	**25 microgram/mL**
menaquinone 7	**40 microgram/mL**

Other Ingredients (Excipients)

dl-alpha-tocopherol
ethanol
glycerol
lecithin
Lemon Oil
medium chain triglycerides
Olive Oil
purified water
tocofersolan
vegetable oil