



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	344046	Ddrops Booster
ARTG entry for	Medicine Listed	
Sponsor	Tycoon Asia Pacific (Australia) Pty Limited	
Postal Address	Unit 17 4a Bachell Avenue, Lidcombe, NSW, 2141 Australia	
ARTG Start Date	22/09/2020	
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 . Ddrops Booster

Product Type	Single Medicine Product	Effective Date	1/02/2021
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children
- Aids/assists teeth development in children
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation in children
- Maintain/support bone health in children
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone strength in children
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Help maintain/support bone mineralisation in children
- 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 cardiovascular system health
- Maintain/support immune system health
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function in children
- Maintain/support healthy neuromuscular system/function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in children

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

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

Indication Requirements

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 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.

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).

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

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

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

No Warnings included on Record

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

colecalfiferol 535.714 microgram/mL

Other Ingredients (Excipients)

medium chain triglycerides

Public Summary

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