



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|---|
| Summary for ARTG Entry: | 302169 | Brauer Baby & Kids Liquid Vitamin D 400IU |
| ARTG entry for | Medicine Listed | |
| Sponsor | BNutrition Pty Ltd | |
| Postal Address | PO Box 234, Tanunda, SA, 5352 Australia | |
| ARTG Start Date | 23/04/2018 | |
| 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 . Brauer Baby & Kids Liquid Vitamin D 400IU

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 30/07/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building in children
- Aids/assists healthy bone development/growth/building in healthy infants
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- 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
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building in children
- Aids/assists healthy bone development/growth/building in healthy infants
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- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate

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

Indication Requirements

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

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.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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 .1 mg/mL

Other Ingredients (Excipients)

dl-alpha-tocopherol

Rice bran oil

vegetable oil

2 . Brauer Baby & Kids Liquid Vitamin D 400IU

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 30/07/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

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Maintain/support bone health

Aids/assists healthy bone development/growth/building in children

Aids/assists healthy bone development/growth/building in healthy infants

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Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

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

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 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

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Warnings

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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 | .1 mg/mL |
|----------------|----------|

Other Ingredients (Excipients)

dl-alpha-tocopherol
 Rice bran oil
 vegetable oil

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