

**Australian Government** 

# **Department of Health**

# Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	302169	Brauer Baby & Kids Liquid Vitamin D 400IU
ARTG entry for	Medicine Listed	
Sponsor	BNutrition Pty Lt	d
Postal Address	PO Box 234, Ta Australia	nunda, SA, 5352
ARTG Start Date	23/04/2018	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	5
- ···		

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

	y & Kids Liquid Vitamin D 400IU		
Product Type	Single Medicine Product	Effective Date	30/07/2022
Permitted Indication	ons		
/laintain/support ge	neral health and wellbeing		
/laintain/support bo	ne health		
ids/assists healthy	bone development/growth/building in children		
ids/assists healthy	bone development/growth/building in healthy infa	ants	
/laintain/support bo	one strength		
lelp maintain/supp	ort bone mineralisation		
laintain/support im	mune system health		
/laintain/support he	althy immune system function		
laintain/support m	uscle function		
laintain/support he	althy neuromuscular system/function		
laintain/support ab	sorption of dietary (state vitamin/mineral/nutrient)		
laintain/support (st	ate vitamin/mineral/nutrient) levels in the body		
lelps prevent dieta	ry (state vitamin/mineral/nutrient) deficiency when	sun exposure is inadequate	
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/laintain/support ge	neral health and wellbeing		
laintain/support bo	ne health		
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elp maintain/supp	ort bone mineralisation		
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laintain/support ab	sorption of dietary (state vitamin/mineral/nutrient)		
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lelps prevent dieta	ry (state vitamin/mineral/nutrient) deficiency when	sun exposure is inadequate	
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## **Department of Health**

# Therapeutic Goods Administration

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 Schedule   Components <ul> <li>I. Formulation 1</li> <li>Dosage Form</li> <li>Oral Liquid</li> <li>Route of Administration</li> <li>Oral</li> <li>Visual Identification</li> <li>Oral</li> <li>Visual Identification</li> <li>Active Ingredients</li> <li>colecalciferol</li> <li>Ing/mL</li> <li>Other Ingredients (Excipients)</li> <li>dhalpha-tocopherol</li> <li>Rice bran oil</li> <li>vegetable oil</li> </ul> 2. Brauer Baby & Kids Liquid Vitamin D 400IU   Product Type   Single Medicine Product   Effective Date   30/07/2022	Pack Size/Poison inf	formation			
1. Formulation 1         Dosage Form       Oral Liquid         Route of Administration       Oral         Visual Identification       Active Ingredients         Active Ingredients       .1 mg/mL         Other Ingredients (Excipients)       .1 mg/mL         Other Ingredients (Excipients)       .1 mg/mL         dl-alpha-tocopherol       .1 mg/mL         Rice bran oil vegetable oil	Pack Size		Poison Schedule		I
Dosage Form       Oral Liquid         Route of Administration       Oral         Visual Identification       Active Ingredients         Active Ingredients       .1 mg/mL         Other Ingredients (Excipients)       .1 mg/mL         dl-alpha-tocopherol       Rice bran oil         Rice bran oil	Components				
Route of Administration Oral   Visual Identification   Active Ingredients   colecalciferol   .1 mg/mL   Other Ingredients (Excipients)   dI-alpha-tocopherol   Rice bran oil   vegetable oil	1. Formulation 1				
Visual Identification Active Ingredients colecalciferol C	Dosage Form	Oral Liquid			
Active Ingredients       .1 mg/mL         Other Ingredients (Excipients)       .1 mg/mL         di-alpha-tocopherol	Route of Administ	ration Oral			
colecalciferol .1 mg/mL Other Ingredients (Excipients) dI-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 Maintain/support general health and wellbeing Maintain/support bone health Aids/assists healthy bone development/growth/building in children	Visual Identificatio	n			
Other Ingredients (Excipients)         dI-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         Maintain/support general health and wellbeing         Maintain/support bone health         Aids/assists healthy bone development/growth/building in children	Active Ingredients	i			
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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 Maintain/support general health and wellbeing Maintain/support bone health Aids/assists healthy bone development/growth/building in children	Other Ingredients	(Excipients)			
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Permitted Indications         Maintain/support general health and wellbeing         Maintain/support bone health         Aids/assists healthy bone development/growth/building in children	2 . Brauer Baby	& Kids Liquid Vitamin D 400IU			
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Maintain/support bone health Aids/assists healthy bone development/growth/building in children	Permitted Indication	S			
Aids/assists healthy bone development/growth/building in children	Maintain/support gene	eral health and wellbeing			
	Maintain/support bone	e health			
Aids/assists healthy bone development/growth/building in healthy infants	Aids/assists healthy b	one development/growth/building in children			
	Aids/assists healthy b	one development/growth/building in healthy infants			
Maintain/support bone strength	Maintain/support bone	e 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

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### **Additional Product information**

Pack Size/Poison informatio	n		
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 (Excipie	ents)		
dl-alpha-tocopherol			
Rice bran oil			
vegetable oil			

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