



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	337775	Floradix Liquid Kindervital Children's Multi
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Endeavour CH Pty Ltd	
<b>Postal Address</b>	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
<b>ARTG Start Date</b>	12/06/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Floradix Liquid Kindervital Children's Multi**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/08/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy levels when dietary intake is inadequate
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support vitality
- Maintain/support healthy growth and development
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children
- Maintain/support healthy teeth
- Maintain/support connective tissue health
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health
- Maintain/support healthy neuromuscular system/function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health

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**Indication Requirements**

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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 mental illnesses, disorders or conditions.

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 musculoskeletal or neurological conditions.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

**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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Oral Liquid
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>calcium gluconate monohydrate</b>	<b>50.35 mg/mL</b>
Equivalent: calcium	4.55 mg/mL
<b>calcium lactate pentahydrate</b>	<b>53.9 mg/mL</b>
Equivalent: calcium	7.5 mg/mL
<b>colecalfiferol</b>	<b>.18 microgram/mL</b>
<b>Coriandrum sativum fruit Infusion</b>	<b>513 mg/mL</b>
Equivalent: Coriandrum sativum (Dry)	1.89 mg/mL
<b>cyanocobalamin</b>	<b>.04 microgram/mL</b>
<b>d-alpha-tocopheryl acetate</b>	<b>.37 mg/mL</b>
<b>Daucus carota root Infusion</b>	<b>513 mg/mL</b>
Equivalent: Daucus carota (Dry)	7.08 mg/mL
<b>Matricaria chamomilla flower Infusion</b>	<b>513 mg/mL</b>
Equivalent: Matricaria chamomilla (Dry)	.59 mg/mL
<b>Nasturtium officinale herb Infusion</b>	<b>513 mg/mL</b>
Equivalent: Nasturtium officinale (Dry)	2.95 mg/mL
<b>nicotinamide</b>	<b>.546 mg/mL</b>
<b>Pimpinella anisum fruit Infusion</b>	<b>513 mg/mL</b>
Equivalent: Pimpinella anisum (Dry)	2.95 mg/mL
<b>pyridoxine hydrochloride</b>	<b>.073 mg/mL</b>
Equivalent: pyridoxine	60 microgram/mL



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<b>retinol palmitate</b>	<b>49.5 microgram/mL</b>
Equivalent: vitamin A	27 RE/millilitre
<b>riboflavine sodium phosphate</b>	<b>90.37 microgram/mL</b>
Equivalent: riboflavine	66 microgram/mL
<b>Spinacia oleracea leaf Infusion</b>	<b>513 mg/mL</b>
Equivalent: Spinacia oleracea (Dry)	1.18 mg/mL
<b>thiamine hydrochloride</b>	<b>.0555 mg/mL</b>
Equivalent: thiamine	42 microgram/mL
<b>Urtica dioica leaf Infusion</b>	<b>513 mg/mL</b>
Equivalent: Urtica dioica (Dry)	1.42 mg/mL

**Other Ingredients (Excipients)**

Acer saccharum  
Acerola  
ascorbic acid  
Ceratonia siliqua  
Flavour  
Grape  
malt extract  
orange  
Pear  
purified water  
Rosa canina

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