



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	180374	Floradix Kindervital Multivitamin & Mineral
ARTG entry for	Medicine Listed	
Sponsor	Endeavour CH Pty Ltd	
Postal Address	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
ARTG Start Date	23/02/2011	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 Kindervital Multivitamin & Mineral

Product Type	Single Medicine Product	Effective Date	23/02/2011
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).

Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults.

Aids, assists or helps in the maintenance or improvement of general well-being.

Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone.

Specific Indications

Floradix Kindervital Vitamin & Mineral Formula with Herbs is in a fruit juice base. Floradix Kindervital for Children is delicious to take and kids just love it. This formulation helps encourage children's natural growth and helps them stay active, fit and alert. Kindervital is rich in Vitamin C and Calcium which supports the formation and maintenance of healthy bones, cartilage and teeth. Kindervital is also a source of B Vitamins and Vitamin D. This combination may be beneficial in the winter months when sunshine is restricted. Maintains or supports nutrient levels in convalescing children.- Helps maintain normal vitality and energy.- Supports general health following illness- Helps maintain/support healthy immune function.- Vitamins and minerals in this formula are essential for growing children. Helps maintain nutrient levels in fussy eaters. Maintains/supports cognitive functions such as concentration, learning and alertness.

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.



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'Contains gluten (or words to that effect)'

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

ascorbic acid	2.4 mg/mL
calcium gluconate monohydrate	51.2 mg/mL
Equivalent: calcium	4.55 mg/mL
calcium lactate pentahydrate	54.8 mg/mL
Equivalent: calcium	7.5 mg/mL
colecalfiferol	.18 microgram/mL
Coriandrum sativum	54.5 mg/mL
Equivalent: Coriandrum sativum	1.92 mg/mL
cyanocobalamin	.04 microgram/mL
d-alpha-tocopheryl acetate	.37 mg/mL
Daucus carota	204.39 mg/mL
Equivalent: Daucus carota	7.2 mg/mL
Matricaria chamomilla	17.03 mg/mL
Equivalent: Matricaria chamomilla	.6 mg/mL
Nasturtium officinale	85.163 mg/mL
Equivalent: Nasturtium officinale	3 mg/mL
nicotinamide	.546 mg/mL
Pimpinella anisum	85.16 mg/mL
Equivalent: Pimpinella anisum	3 mg/mL
pyridoxine hydrochloride	.073 mg/mL
Equivalent: pyridoxine	60 microgram/mL
retinol palmitate	49.5 microgram/mL
Equivalent: vitamin A	27 RE/millilitre
riboflavine sodium phosphate	.087 mg/mL
Equivalent: riboflavine	66 microgram/mL
Rosa canina	36 mg/mL
Equivalent: ascorbic acid	1.44 mg/mL
Equivalent: Rosa canina	36 mg/mL
Spinacia oleracea	34.065 mg/mL
Equivalent: Spinacia oleracea	1.2 mg/mL
thiamine hydrochloride	.0554 mg/mL
Equivalent: thiamine	42 microgram/mL
Urtica dioica	40.88 mg/mL
Equivalent: Urtica dioica	1.44 mg/mL

Other Ingredients (Excipients)

Acer saccharum

Acerola

Ceratonia siliqua

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Flavour
Grape
malt extract
Orange
Pear
purified water

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