

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 330311 Kids Multi +

ARTG entry for Medicine Listed

Sponsor JSHealth Vitamins Pty Ltd

Postal Address 17 Kimberley Street, Vaucluse, NSW, 2030

Australia

ARTG Start Date 24/02/2020
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 . Kids Multi +

Product Type Single Medicine Product Effective Date 9/01/2023

Permitted Indications

Maintain/support energy production

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Maintain/support teeth strength

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

Aid/assist healthy red blood cell production

Helps maintain/support healthy blood sugar/glucose

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Maintain/support muscle function

Maintain/support muscle strength

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support cognitive development

Maintain/support brain function

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support skin health

Maintain/support wound healing

Antioxidant/Reduce free radicals formed in the body

Maintain/support healthy growth and development in children

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Indication Requirements

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to neurological conditions or developmental delays.

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

Product presentation must not imply or refer to serious cardiovascular 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.

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).

Label statement: If symptoms persist, talk to your health professional.

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 Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid 15 mg

Biotin 100 microgram

calcium folinate 108.5 microgram

Equivalent: folinic acid 100 microgram

calcium hydrogen phosphate 33.94 mg

Equivalent: calcium 10 mg

calcium pantothenate 5 mg

Equivalent: pantothenic acid 4.58 mg

chromic chloride hexahydrate 128 microgram

Equivalent: chromium 25 microgram

Citrus bioflavonoids extract 5 mg

colecalciferol 2.5 microgram cyanocobalamin 50 microgram

d-alpha-tocopheryl acid succinate 8.265 mg
ferrous fumarate 3.05 mg

Equivalent: iron 1 mg

lysine hydrochloride12.5 mgEquivalent: lysine10 mg

magnesium phosphate pentahydrate50 mgEquivalent: magnesium10.33 mg

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manganese (II) glycinate 313 microgram

Equivalent: manganese 50 microgram

nicotinamide 6 mg

Passiflora incarnata herb flowering Extract dry concentrate 5 mg

Equivalent: Passiflora incarnata (Dry) 25 mg

potassium iodide65 microgramEquivalent: iodine50 microgram

pyridoxine hydrochloride5 mgEquivalent: pyridoxine4.11 mg

retinol acetate 68.8 microgram

Equivalent: vitamin A 59.98 RE riboflavin 2.5 mg thiamine nitrate 2.5 mg zinc citrate dihydrate 9.355 mg

Other Ingredients (Excipients)

Acacia

beetroot

butylated hydroxytoluene

citric acid

dl-alpha-tocopherol

Equivalent: zinc

Flavour

magnesium stearate

maize starch

malto dextrin

medium chain triglycerides

rice starch
silicon dioxide
sodium bicarbonate

sucrose thaumatin

xylitol

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