# **Department of Health**

# Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry: 329564 Kids Multi

ARTG entry for Medicine Listed

Sponsor Factors Group Australia Pty Ltd

Postal Address Unit B 10-16 South Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 6/02/2020
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.

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.

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 . Kids Multi

Product Type Single Medicine Product Effective Date 27/03/2020

## **Permitted Indications**

Maintain/support healthy growth and development

Maintain/support general health and wellbeing

Maintain/support immune system health

Maintain/support healthy immune system function

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

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

Maintain/support (state vitamin/mineral) within normal range

Maintain/support cognitive function/mental function

## **Indication Requirements**

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 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 mental illnesses, disorders or conditions.

## **Standard Indications**

No Standard Indications included on Record

## Specific Indications

No Specific Indications included on Record

## Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

#### **Additional Product information**

## Pack Size/Poison information

Poison Schedule **Pack Size** 

## Components

## 1 . Formulation 1

Dosage Form Tablet, uncoated

**Route of Administration** Oral

Visual Identification

## **Active Ingredients**

Apium graveolens seed Extract dry concentrate 2 mg Equivalent: Apium graveolens (Dry) 20 mg

Apium graveolens herb top Extract dry concentrate 320 microgram

Equivalent: Apium graveolens (Fresh)

Ascophyllum nodosum whole plant Powder standardised 9.375 mg

Beta vulgaris root Powder 2 mg

Beta vulgaris root Extract dry concentrate 284 microgram

Equivalent: Beta vulgaris (Fresh) 2.84 mg 3.2895 mg

borax

Equivalent: boron

Brassica oleracea var. botrytis herb top Extract dry concentrate 290 microgram

Equivalent: Brassica oleracea var. botrytis (Fresh) 4.35 mg Brassica oleracea var. botrytis herb top Powder 3 mg Brassica oleracea var. capitata leaf Powder 3 mg

Brassica oleracea var. capitata herb top Extract dry concentrate 588 microgram

Equivalent: Brassica oleracea var. capitata (Fresh) 26.46 mg Brassica oleracea var. italica herb top Powder 3 mg

Brassica oleracea var. viridis leaf Extract dry concentrate 52 microgram

Equivalent: Brassica oleracea var. viridis (Fresh) 208 microgram Brassica oleracea var. viridis herb top Powder 2 ma

calcified lithothamnion species 13.217 mg

Equivalent: calcium 4.174 ma calcium ascorbate 18.147 mg Equivalent: ascorbic acid

15 mg Equivalent: calcium 1.826 mg 2.976 mg calcium pantothenate Equivalent: calcium .25 ma

Equivalent: pantothenic acid 2.5 ma

Capsicum annuum fruit Extract dry concentrate 416 microgram

Equivalent: Capsicum annuum (Fresh) 8.32 mg

chromium picolinate 80.45 microgram Equivalent: chromium 10 microgram colecalciferol .0062 mg

Coriandrum sativum leaf Powder 2 mg

Coriandrum sativum leaf Extract dry concentrate 26 microgram Equivalent: Coriandrum sativum (Fresh) 26 microgram cupric sulfate pentahydrate 392.8 microgram

Equivalent: copper 100 microgram

4.8 mg

375 microgram



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Cynara scolymus flower bud Extract dry	2 microgram
Equivalent: Cynara scolymus (Fresh)	1.197 microgram
Cynara scolymus leaf Powder	2 mg
d-alpha-tocopherol	5 mg
Echinacea purpurea herb top Extract dry concentrate	140 microgram
Equivalent: Echinacea purpurea (Fresh)	980 microgram
Eruca sativa leaf Powder	3 mg
ferric pyrophosphate	16.678 mg
Equivalent: iron	5 mg
Fragaria vesca fruit Powder	.2 mg
Hordeum vulgare leaf Powder	2 mg
Laminaria japonica whole plant Powder	576 microgram
levomefolate glucosamine	370.37 microgram

Equivalent: levomefolic acid

200 microgram

lutein

15 mg

lycopene

15 mg

 lycopene
 .5 mg

 Lycopersicon esculentum fruit Extract dry concentrate
 212 microgram

 Equivalent: Lycopersicon esculentum (Fresh)
 636 microgram

 Lycopersicon esculentum fruit Powder
 2.25 mg

 Iysine hydrochloride
 3.123 mg

 Equivalent: lysine
 2.5 mg

 magnesium ascorbate
 7.07 mg

Equivalent: magnesium .707 mg Equivalent: ascorbic acid 5 mg 7.715 mg magnesium aspartate Equivalent: magnesium 1.543 mg magnesium citrate 24.691 mg Equivalent: magnesium 4 mg manganese gluconate 10.965 ma Equivalent: manganese 1.25 mg

mecobalamin (co-methylcobalamin)100 microgramMedicago sativa leaf Extract dry concentrate2.74 mgEquivalent: Medicago sativa (Fresh)68.5 mg

menaquinone 7

Mentha spicata herb top Extract dry concentrate

Equivalent: Mentha spicata (Fresh)

Mentha X piperita herb top Extract dry concentrate

330 microgram

Equivalent: Mentha X piperita (Fresh)

2.97 mg

Nasturtium officinale leaf Extract dry

Equivalent: Nasturtium officinale (Fresh)

11.2 microgram

Nasturtium officinale leaf Powder

2 mg

nicotinamide 6.25 mg Origanum vulgare herb top Extract dry concentrate 62 microgram Equivalent: Origanum vulgare (Fresh) 248 microgram Petroselinum crispum herb top Extract dry concentrate 1.234 mg Equivalent: Petroselinum crispum (Fresh) 24.68 mg Petroselinum crispum leaf Powder 2 mg Phyllanthus emblica fruit Extract dry concentrate standardised 5 mg Equivalent: Phyllanthus emblica (Dry) 250 mg Punica granatum fruit Powder .2 mg

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1.015 mg

pyridoxal 5-phosphate monohydrate



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Equivalent: pyridoxine .625 mg Raphanus sativus root Powder 2 mg Raphanus sativus root Powder 6 mg riboflavin sodium phosphate .855 mg Equivalent: riboflavin .625 mg Rubus idaeus fruit Powder .2 ma selenomethionine 62.09 microgram Equivalent: selenium 25 microgram

Taraxacum officinale root Powder 2 mg thiamine hydrochloride .794 mg Equivalent: thiamine .625 mg Vaccinium macrocarpon fruit Powder .2 mg Vaccinium myrtillus fruit Powder .2 mg Vitis vinifera seed Extract dry concentrate 17.2 mg Equivalent: Vitis vinifera (Dry) 636.4 mg Vitis vinifera seed Extract dry concentrate 1.6 mg Equivalent: Vitis vinifera (Dry) 160 mg zinc citrate 18.302 mg

# Other Ingredients (Excipients)

## Acacia

ascorbyl palmitate

Equivalent: zinc

calcium hydrogen phosphate chlorophyllin-copper complex

citric acid

colloidal anhydrous silica

d-alpha-tocopherol

dl-alpha-tocopherol

Flavour glucose

hydrolysed maize starch

lecithin

magnesium stearate

maize starch maltodextrin

maltose

microcrystalline cellulose

mixed (high-alpha type) tocopherols concentrate

mono- and di- glycerides pregelatinised maize starch

purified water silicon dioxide Siraitia grosvenorii sodium ascorbate

sodium chloride

starch sodium octenyl succinate

stearic acid Stevia rebaudiana sucrose xylitol 6.25 mg



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