



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	289492	BLACKMORES SUPERKIDS MULTI CHEWABLES
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	30/05/2017	
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 . BLACKMORES SUPERKIDS MULTI CHEWABLES

Product Type	Single Medicine Product	Effective Date	10/06/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support brain function
- Maintain/support brain/central nervous system development

Indication Requirements

- If product is indicated for supplementation, Label statement: 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.
- Product presentation must not imply or refer to neurological conditions or developmental delays.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

Additional Product information



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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	10 mg
Biotin	25 microgram
calcium hydrogen phosphate	17 mg
Equivalent: calcium	5 mg
Equivalent: phosphorus	3.87 mg
calcium pantothenate	1.635 mg
Equivalent: pantothenic acid	1.5 mg
Equivalent: calcium	137 microgram
colecalfiferol	.0025 mg
cyanocobalamin	.75 microgram
d-alpha-tocopheryl acid succinate	12.4 mg
Equivalent: d-alpha-tocopheryl acid succinate	15 IU
ferrous fumarate	3.804 mg
folic acid	50 microgram
magnesium phosphate tribasic	24.2 mg
Equivalent: magnesium	5 mg
manganese amino acid chelate	125 microgram
Equivalent: manganese	12.5 microgram
nicotinamide	5.994 mg
potassium iodide	98.3 microgram
Equivalent: iodine	75 microgram
pyridoxine hydrochloride	.6493 mg
retinol acetate	.2018 mg
riboflavine	.5511 mg
sodium ascorbate	11.3 mg
Equivalent: ascorbic acid	10 mg
thiamine nitrate	.3496 mg
zinc oxide	1.24 mg
Equivalent: zinc	1 mg

Other Ingredients (Excipients)

- butylated hydroxytoluene
- colloidal anhydrous silica
- dl-alpha-tocopherol
- Flavour
- Gelatin
- hydrogenated soya oil
- hydrolysed gelatin
- hypromellose
- magnesium stearate
- maize starch
- mannitol



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microcrystalline cellulose

mono- and di- glycerides

silicon dioxide

Stevia rebaudiana

sucrose

xylitol

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