



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

## Public Summary

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

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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

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

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 neurological conditions or developmental delays.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

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



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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**

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