



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	326235	Extra Strength Acne Control
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SkinB5 Pty Ltd	
<b>Postal Address</b>	PO Box 147, Ringwood, VIC, 3134 Australia	
<b>ARTG Start Date</b>	14/11/2019	
<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.

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 . Extra Strength Acne Control**

Product Type	Effective Date
Single Medicine Product	14/11/2019

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Aid/assist/help/maintain healthy hair follicles
- Aid/assist nail growth
- Enhance/improve/promote immune defence/immunity
- Maintain/support healthy immune system function
- Enhance/promote body adaptation to stress
- Support healthy body stress recovery
- Decrease/reduce/relieve symptoms of stress
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Relieve symptoms of acne
- Decrease/reduce/relieve congested skin pores
- Relieve minor skin eruptions
- Decrease/reduce/relieve symptoms of acne blackheads
- Helps reduce occurrence of symptoms of acne
- Decrease/reduce/relieve pimples
- Helps reduce occurrence of pimples
- Soothe skin
- Soothe/relieve skin inflammation

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Decrease/reduce/relieve skin redness  
 Maintain/support skin health  
 Helps enhance/improve skin internal structure  
 Helps enhance/improve skin strength  
 Enhance/improve healing of minor skin wound/cuts/scratches/abrasions  
 Enhance/improve/promote skin repair/healing

**Indication Requirements**

Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to infertility.  
 Product presentation must not imply or refer to hormone imbalances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.  
 If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.  
 WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).  
 The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

1 . Formulation 1

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Biotin</b>	<b>625 microgram</b>
<b>calcium pantothenate</b>	<b>655.08 mg</b>
Equivalent: pantothenic acid	600 mg
<b>colloidal anhydrous silica</b>	<b>26.738 mg</b>
Equivalent: silicon	12.5 mg
<b>copper gluconate</b>	<b>2.97 mg</b>
Equivalent: copper	412.5 microgram
<b>folic acid</b>	<b>125 microgram</b>
<b>nicotinamide</b>	<b>225 mg</b>
<b>retinol acetate</b>	<b>280.98 microgram</b>
Equivalent: vitamin A	245 RE
<b>Urtica dioica root Dry</b>	<b>150 mg</b>
Equivalent: Urtica dioica (Dry)	1.5 g
<b>Vitex agnus-castus fruit Extract dry concentrate</b>	<b>12.5 mg</b>
Equivalent: Vitex agnus-castus (Fresh)	125 mg
<b>zinc gluconate</b>	<b>57.59 mg</b>
Equivalent: zinc	8.25 mg

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**Other Ingredients (Excipients)**

calcium hydrogen phosphate  
Carnauba Wax  
crospovidone  
lecithin  
macrogol 3000  
magnesium stearate  
microcrystalline cellulose  
polyvinyl alcohol  
purified talc  
titanium dioxide

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