



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

## Public Summary

<b>Summary for ARTG Entry:</b>	367067	Extra Strength Acne Control Tablet
<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>	25/05/2021	
<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.

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 Tablet

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/04/2022
---------------------	-------------------------	-----------------------	------------

### 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  
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



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

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

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

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to hormone imbalances.

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

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

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).

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

#### Additional Product information

#### Pack Size/Poison information

Pack Size	Poison Schedule
-----------	-----------------

#### Components

##### 1 . Formulation 1

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

#### Visual Identification

#### Active Ingredients

<b>Biotin</b>	<b>500 microgram</b>
<b>calcium pantothenate</b>	<b>545.9 mg</b>
Equivalent: pantothenic acid	500 mg
Equivalent: calcium	45.8 mg
<b>colloidal anhydrous silica</b>	<b>26.74 mg</b>
Equivalent: silicon	12.5 mg
<b>copper gluconate</b>	<b>2.68 mg</b>
Equivalent: copper	375 microgram
<b>folic acid</b>	<b>125 microgram</b>
<b>nicotinamide</b>	<b>187.5 mg</b>
<b>retinol acetate</b>	<b>.2064 mg</b>
Equivalent: vitamin A	.175 mg
<b>Urtica dioica root Extract dry concentrate</b>	<b>93.75 mg</b>
Equivalent: Urtica dioica (Dry)	1.5 g
<b>zinc gluconate</b>	<b>57.43 mg</b>
Equivalent: zinc	7.5 mg

#### Other Ingredients (Excipients)

**Acacia**

**calcium hydrogen phosphate dihydrate**

**Carnauba Wax**

**crospovidone**

**dl-alpha-tocopherol**

**lecithin**

Public Summary



## Australian Government

### Department of Health Therapeutic Goods Administration

macrogol 3000  
magnesium stearate  
maize starch  
microcrystalline cellulose  
polyvinyl alcohol  
povidone  
purified talc  
spray-dried glucose syrup  
titanium dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary