



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	367067	Extra Strength Acne Control Tablet
ARTG entry for	Medicine Listed	
Sponsor	SkinB5 Pty Ltd	
Postal Address	PO Box 147, Ringwood, VIC, 3134 Australia	
ARTG Start Date	25/05/2021	
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.

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

Product Type	Single Medicine Product	Effective Date	27/04/2022
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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



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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

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.
 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
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
crospovidone
dl-alpha-tocopherol
lecithin

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

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