Public Summary

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

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	Single Medicine Product	**Effective Date**	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

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

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 mental illnesses, disorders or conditions.

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

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

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

Other Ingredients (Excipients)

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