



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

## Public Summary

<b>Summary for ARTG Entry:</b>	93556	Cutis compositum
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Professional Pty Ltd	
<b>Postal Address</b>	PO Box 174, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	19/03/2003	
<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 . Cutis compositum

Product Type	Single Medicine Product	Effective Date	9/07/2019
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#### Permitted Indications

- Traditionally used in Homoeopathic medicine to relieve symptoms of acne
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve skin dryness

#### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild eczema.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

- Contains lactose (or words to that effect).
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
- Homoeopathic product/preparation or medicine (or words to that effect)
- If symptoms persist consult your healthcare practitioner (or words to that effect).
- This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, uncoated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Aesculus hippocastanum seed (Homeopathic)</b>	<b>1 mg</b>
<b>Arctium lappa root (Homeopathic)</b>	<b>1 mg</b>
<b>calcium fluoride (Homeopathic)</b>	<b>1 mg</b>
<b>cortisone acetate (Homeopathic)</b>	<b>1 mg</b>
<b>formic acid (Homeopathic)</b>	<b>1 mg</b>
<b>fumaric acid (Homeopathic)</b>	<b>1 mg</b>
<b>Galium aparine herb flowering (Homeopathic)</b>	<b>1 mg</b>
<b>hahnemann's soluble mercury (Homeopathic)</b>	<b>1 mg</b>
<b>ichthammol (Homeopathic)</b>	<b>1 mg</b>
<b>Ledum palustre twig leafy (Homeopathic)</b>	<b>1 mg</b>
Equivalent: Arbutin	.2 picogram
<b>phosphoric acid (Homeopathic)</b>	<b>1 mg</b>
<b>Porcine (Homeopathic)</b>	<b>1 mg</b>
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<b>Porcine (Homeopathic)</b>	<b>1 mg</b>
<b>selenium (Homeopathic)</b>	<b>1 mg</b>
<b>Strychnos ignatii seed (Homeopathic)</b>	<b>1 mg</b>
Equivalent: strychnine (of Strychnos spp.)	36 picogram
<b>sublimed sulfur (Homeopathic)</b>	<b>1 mg</b>
<b>Thuja occidentalis shoot top (Homeopathic)</b>	<b>1 mg</b>
<b>Urtica urens whole plant (Homeopathic)</b>	<b>1 mg</b>

**Other Ingredients (Excipients)**

**lactose monohydrate**  
**magnesium stearate**

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