



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	73356	SEBIZOLE ketoconazole 1% w/w shampoo bottle
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Medis Pharma Pty Ltd	
<b>Postal Address</b>	Locked Bag 2053, North Ryde, NSW, 1670 Australia	
<b>ARTG Start Date</b>	22/03/2000	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Non-Prescription Medicines	

**Conditions**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

**Products**

**1 . SEBIZOLE ketoconazole 1% w/w shampoo bottle**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/08/2005
---------------------	-------------------------	-----------------------	-----------

**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Topical treatment of moderate to severe dandruff in adults. Sebizole Shampoo provides only temporary relief during the period of use.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
200mL	Not scheduled. Not considered by committee
100mL	Not scheduled. Not considered by committee
20mL	Not scheduled. Not considered by committee

**Components**

**1 . Medicine Component**

<b>Dosage Form</b>	Application
<b>Route of Administration</b>	Topical
<b>Visual Identification</b>	A clear, pink coloured, viscous liquid with a fragrance smell.

**Active Ingredients**

<b>ketoconazole</b>	<b>10.5 mg/mL</b>
---------------------	-------------------

**Other Ingredients (Excipients)**

Public Summary



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

cocamide DEA  
erythrosine  
Fragrance (perfume)  
hydrochloric acid  
PEG-150 distearate  
purified water  
sodium laureth sulfate  
sodium lauroyl sarcosinate

---

© 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