



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	91036	GRANGE ACTIVE SKIN LIGHTENING CREAM
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Lady Alexander Pty Ltd	
Postal Address	Level 13 / 256 Adelaide Terrace, PERTH, WA, 6000 Australia	
ARTG Start Date	17/09/2002	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

Products

1 . GRANGE ACTIVE SKIN LIGHTENING CREAM

Product Type	Single Medicine Product	Effective Date	17/09/2002
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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

THE REDUCTION OF SKIN PIGMENTATION

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
export	Not scheduled. Not considered by committee

Components

1 . CREAM

Dosage Form	Cream
Route of Administration	Topical

Visual Identification

Active Ingredients

hydroquinone	20 mg/g
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Australian Government
Department of Health
Therapeutic Goods Administration

octyl methoxycinnamate	50 mg/g
oxybenzone	15 mg/g

Other Ingredients (Excipients)

cetareth-20
citric acid
d-alpha-tocopheryl acetate
dimeticone 350
Fragrance (perfume)
glycerol
glyceryl monostearate
isopropyl myristate
lecithin
liquid paraffin
methyl hydroxybenzoate
panthenol
polysorbate 20
propyl hydroxybenzoate
propylene glycol monolaurate
propylene glycol monostearate
self-emulsifying glyceryl monostearate
sodium metabisulfite
sorbitan monolaurate
stearyl alcohol
stearyl stearate
titanium dioxide
water for injections
Wool alcohols
Wool fat

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