



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 81770 SOUL PATTINSON ANTIFUNGAL CLOTRIMAZOLE WOMEN'S COMBINATION TREATMENT 500mg pessary strip pack and 10mg/g cream tube composite pack

ARTG entry for Medicine Registered
Sponsor Soul Pattinson Manufacturing Pty Ltd
Postal Address Locked Bag 5061, PARRAMATTA, NSW, 2124 Australia
ARTG Start Date 21/02/2002
Product Category Medicine
Status Active
Approval Area 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 . SOUL PATTINSON ANTIFUNGAL CLOTRIMAZOLE WOMEN'S COMBINATION TREATMENT pessary and cream

Product Type	Composite Pack	Effective Date	3/07/2002
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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

For the treatment of vulvovaginal candidiasis and cutaneous candidiasis in the genital area of the partner.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1x20g cream plus 1x500mg pessary plus an applicator	(S3) Pharmacist Only Medicine
1x30g cream plus 500mg pessary plus an applicator	(S3) Pharmacist Only Medicine

Components

1 . Cream

Dosage Form Cream
Route of Administration Topical
Visual Identification White, smooth, homogenous cream.

Active Ingredients

clotrimazole **10 mg/g**



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Other Ingredients (Excipients)

benzyl alcohol
cetostearyl alcohol
cetyl esters wax
dibasic sodium phosphate
monobasic sodium phosphate
octyldodecanol
polysorbate 60
purified water
sorbitan monostearate

2 . Pessary

Dosage Form Pessary, compressed
Route of Administration Vaginal
Visual Identification White pessaries.

Active Ingredients

clotrimazole 500 mg

Other Ingredients (Excipients)

adipic acid
colloidal anhydrous silica
lactose monohydrate
magnesium stearate
maize starch
microcrystalline cellulose
polysorbate 80
pregelatinised maize starch
sodium bicarbonate
stearic acid

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