CLOTRIMAZOLE- clotrimazole cream Rebel Distributors Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Perrigo Clotrimazole Cream USP, 1% Drug Facts

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

Warnings

For external use only

Do not use

on children under 2 years of age unless directed by a doctor

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash the affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot pay special attention to the spaces between the toes, wear well-fitting ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, consult a doctor
- this product is not effective on the scalp or nails

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Questions or comments?

1-800-719-9260

Principal Display Panel

Cures Most Athlete's Foot

Relieves Itching & Burning

Greaseless, Non-Staining

Compare to Lotrimin® AF active ingredient

Clotrimazole Cream USP, 1%

Antifungal



CLOTRIMAZOLE

clotrimazole cream

| Product Information | | | | |
|-------------------------|----------------|--------------------|------------------------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42254-030(NDC:45802-434) | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|--------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) | CLOTRIMAZOLE | 1 g in 100 g | |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| CETYL ESTERS WAX (UNII: D072FFP9GU) | | | | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | | | | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X) | | | | |

| Packaging | | | | |
|-------------|-----------|---------------------|----------------------|--------------------|
| # Item | Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:42254 | -030-15 1 | in 1 CARTON | | |
| 1 | 1 | 5 g in 1 TUBE | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333C | 06/03/2011 | | |
| | | | | |

Labeler - Rebel Distributors Corp (118802834)

| Establishment | | | | |
|-------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Rebel Distributors Corp | | 118802834 | RELABEL, REPACK | |

Revised: 12/2011 Rebel Distributors Corp