

AU KAH CHUEN ANTIFUNGAL- clotrimazole lotion
ANHUI DONGSHENGYOUBANG PHARMACEUTICAL CO., LTD.

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.

Drug Facts

Active Ingredient

Clotrimazole 1.0%

Purpose

Antifungal

Uses

Proven clinically effective in the treatment of most:
athlete's foot
jock itch
ringworm

Warnings

For external use only

Flammable

Keep away from fire or flame.

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:

2 weeks when used for jock itch

4 weeks when used for athlete's foot or ringworm

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 of the product over the affected area twice daily (morning and night) or as directed by a doctor.

Supervise children in the use of this product.

For athlete's foot:

Pay special attention to spaces between the toes.

Wear well-fitting, ventilated shoes.

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

Keep container tightly closed, away from heat
Store at 2° to 30° C (36° to 86° F)

Inactive Ingredients

Glycerin, isopropyl alcohol, musk xylol, phenol and purified water.

Questions or Comments? (888) 221-3496 M-F, 9am to 5pm
you may also report serious side effects to the phone number.

AU KAH CHUEN ANTIFUNGAL LOTION
NDC 72030-100-01
0.81 fl oz (24 mL)



AU KAH CHUEN ANTIFUNGAL

clotrimazole lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72030-100 |
| 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 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| MUSK XYLENE (UNII: 1ZAO16GU5K) | |
| PHENOL (UNII: 339NCG44TV) | |
| WATER (UNII: 059QF0K00R) | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72030-100-01 | 1 in 1 BOX | 11/26/2018 | |
| 1 | | 24 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part333C | 11/26/2018 | |

Labeler - ANHUI DONGSHENGYOUBANG PHARMACEUTICAL CO., LTD. (527929527)

| Establishment | | | |
|---|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| ANHUI DONGSHENGYOUBANG PHARMACEUTICAL CO., LTD. | | 527929527 | manufacture(72030-100) |

Revised: 11/2018

ANHUI DONGSHENGYOUBANG PHARMACEUTICAL CO., LTD.