BUDPAK ANTIFUNGAL CLOTRIMAZOLE- clotrimazole cream
Budpak Inc.

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.

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

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

For external use only

When using this product avoid contact with eyes.

Stop using this product and ask a doctor

- irritation occurs
- there is no improvement within 4 weeks (for athlete’s foot and ringworm) or 2 weeks (for jock itch).
- do not use for diaper rash

Keep this and all drugs out of reach of children.

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

Directions

- wash affected area and dry thoroughly
- Apply a thin layer over 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 and change shoes and socks at least once a day
- for athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- if conditions persist longer, ask a doctor
- this product is not effective on the scalp or nails.

Other information

- Store between 20°C to 25° C (68°F to 77°F)
- Lot No. & Exp. Date: see crimp of tube.

Inactive ingredients

Purified Water, Mineral Oil, Cetearyl Alcohol, Petrolatum, Glyceryl Stearate, Propylene Glycol, Polysorbate 60, Sorbitan mono stearate, Methylparaben, Propylparaben.

PRINCIPAL DISPLAY PANEL

Budpak Antifungal Cream

Clotrimazole 1%

NET WT 0.5 OZ (14 g)

BUDPAK ANTIFUNGAL CLOTRIMAZOLE

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-025

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-025-01	1 in 1 BOX		
1	NDC:27293-025-14	14 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/17/2012	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-025)

Revised: 11/2012 Budpak Inc.