

BLOSSOM PHARMACEUTICALS ANTIFUNGAL- antifungal cream

Blossom Pharmaceuticals

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.

Antifungal Cream

Active Ingredient

Active Ingredient	Purpose
Clotrimazole 1.0%	Antifungal

Purpose

- For treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis).
- For the treatment of superficial skin infections caused by Yeast (Candida Albicans).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation discomfort and chafing associated with jock itch.

Warnings

Do not use:

- Do not use on children under 2 years of age unless directed by a doctor.
- Avoid contact with eyes.
- For athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- For jock itch - if irritation occurs, or if there is no improvement within two weeks, discontinue use and consult a doctor.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Indications and Usage

- Clean the affected area and dry thoroughly. Apply a layer of cream 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 toes: wear well fitting, ventilated shoes, and change shoes and socks at least once daily.

Dosage and Administration

- For athlete's foot and ringworm, use daily for 4 weeks.
- For jock itch, use daily for 2 weeks. If conditions persist longer, consult a doctor.
- This product is not effective on scalp or nails.

Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

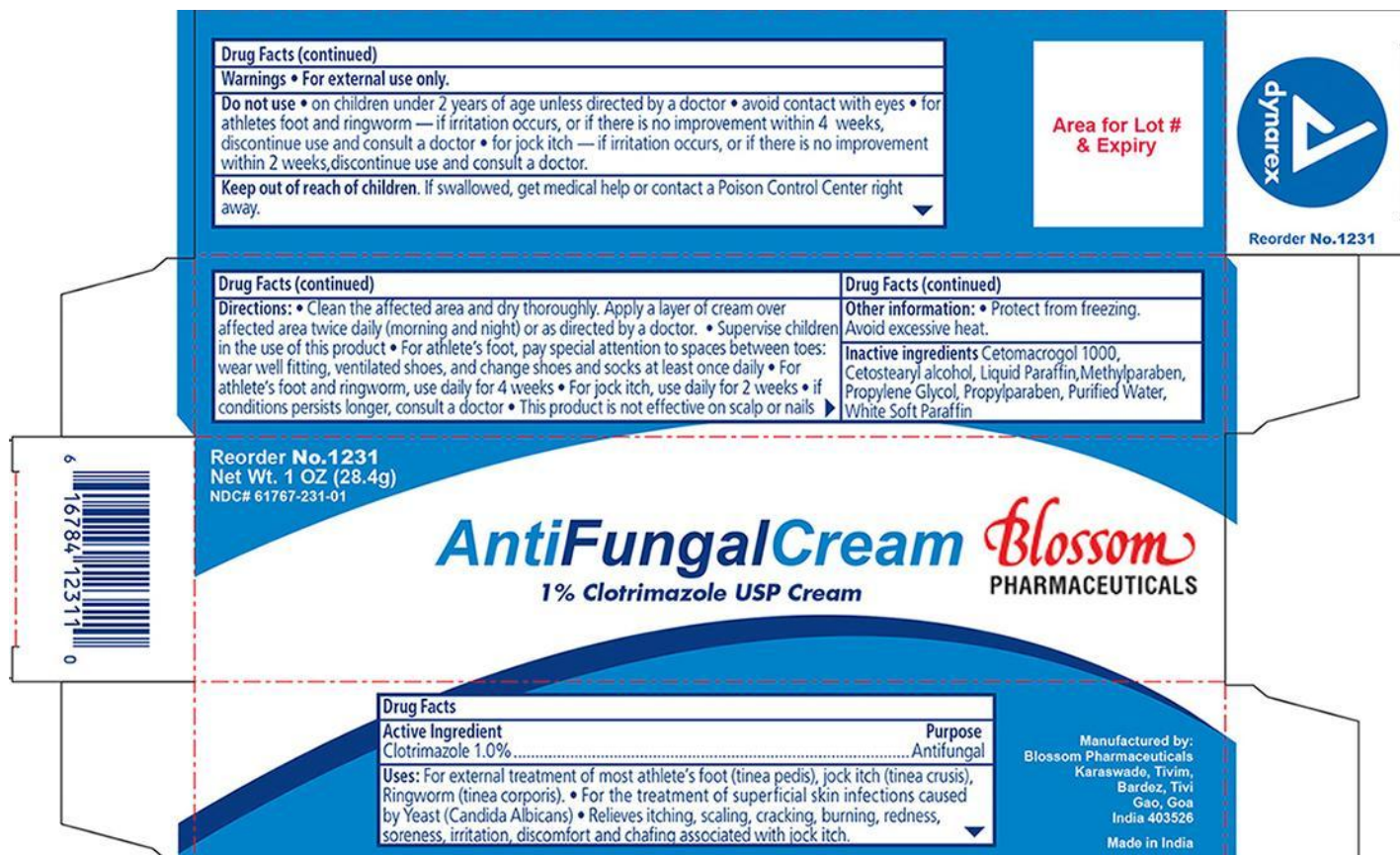
INACTIVE INGREDIENTS

Inactive Ingredients: Cetomicrogol 1000, Cetostearyl alcohol, Liquid paraffin, Methylparaben, Propylene glycol, Propylparaben, Purified water, White soft paraben

Principal Display Panel

Blossom Antifungal Cream

Blossom Antifungal.jpg



BLOSSOM PHARMACEUTICALS ANTIFUNGAL

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1767-231
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
CETETH-20 (UNII: I835H2IHHX)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61767-231-02	28.25 g in 1 TUBE		
2	NDC:61767-231-01	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/09/2014	

Labeler - Blossom Pharmaceuticals (677381470)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(61767-231)

Revised: 5/2014

Blossom Pharmaceuticals