

FUNGUS RELIEF - tolnaftate solution

Swabplus 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.

Fungus Relief Swab

Drug Facts

Active Ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Cures fungal infections of the toes and fingers, including skin around and under nails, where accessible with swab applicator. Cures most athlete's foot (tinea pedis) and ringworm (tinea corporis) and relieves symptoms of athlete's foot including itching, burning and scaly skin.
- Help prevent most athlete's foot from recurring when uses daily.

Warnings

For external use only.

When using this product avoid contact with eyes.

Stop use and ask a doctor if irritation occurs. there is no improvement within 4 weeks.

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

Keep out of the reach of children

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

Directions

- Do not use if label seal is broken prior to purchase.
- Keep swabs in original container when not in use.
- wash affected area and dry thoroughly.
- Hold the swab vertically with the color band tip upwards.
- Bend the tip at the color band to one side until it snaps.
- Apply a thin layer over affected area twice daily (morning and night)
- Discard swab after use.
- For athlete's foot, apply once or twice daily, pay special attention to spaces between toes, wear shoes with good ventilation and change shoes and socks at least once daily.
- Use daily for 4 weeks; if condition persists longer, ask a doctor.
- This product is not effective on the scalp or nails.

Other information

Avoid storing at excessive heat.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, BHT, Butylene Glycol, Diazolidinyl Urea, Ethoxydiglycol, Methylparaben, Propylene Glycol, Propylparaben, Tocopheryl Acetate

Image of carton label



FUNGUS RELIEF			
tolnaftate solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65734-348
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-348-36	36 in 1 PACKAGE		
1	NDC:65734-348-00	0.15 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/01/2003	

Labeler - Swabplus Inc. (876441549)**Registrant** - Swabplus Inc. (876441549)**Establishment**

Name	Address	ID/FEI	Business Operations
Swabplus Inc.		876441549	manufacture(65734-348) , relabel(65734-348) , repack(65734-348)

Revised: 1/2015

Swabplus Inc.