KENDALL ANTIFUNGAL - miconazole nitrate cream Covidien 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.

Kendall Antifungal Cream

Active Ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis).
- for effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort, and chafing associated with jock itch.

Warnings

Do not use on children under two years old unless directed by a doctor. **For external use only.**

When using this product

• do not get into eyes

For the treatment of athlete's foot and ringworm, if irritation occurs or if there is no improvement within four weeks, discontinue use and consult a doctor.

For the treatment of jock itch, if irritation occurs or if there is no improvement within two weeks, discontinue use and consult a doctor.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions Clean 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 and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for four weeks; for jock itch, use daily for two weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

Other Information

- protect from freezing
- avoid excessive heat

Inactive ingredients

Water, mineral oil propylene glycol, sorbitane stearate, cetyl alcohol, isopropyl palmitate, simmondsia

chinensis (jojoba) seed oil, sodium lactate, polysorbate 60, dimethicone, butyrospermum parkii (shea butter), decylene glycol, xanthan gum, retinyl palmitate, tocopheryl acetate, cetyl hydroxyethylcellulose, methylparaben, propylparaben, diazolidinyl urea

Questions or comments? 1-800-962-9888

Image of Antifungal Cream 4 oz Label

Drug Facts **Active ingredient** Purpose Miconazole nitrate 2% ... Antifungal **Uses** • for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis). for effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort, and chafing associated with jock itch. Warnings Do not use on children under two years old unless directed by a doctor. For external use only. When using this product = do not get into eyes For the treatment of athlete's foot and ringworm, if irritation occurs or if there is no improvement within four weeks, discontinue use and consult a doctor. For the treatment of jock itch, if irritation occurs or 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. **Directions** Clean 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 and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for four weeks; for jock itch, use daily for two weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails. Other information protect from freezing avoid excessive heat Inactive ingredients Water, mineral oil, propylene glycol, sorbitane stearate, cetyl alcohol, isopropyl palmitate, simmondsia chinensis (jojoba) seed oil, sodium lactate, polysorbate 60, dimethicone, butyrospermum parkii (shea butter), decylene glycol, xanthan gum, retinyl palmitate, tocopheryl acetate, cetyl hydoxyethylcellulose, methylparaben, propylparaben, diazolidinyl urea 20884521064420 **Questions or comments?** 1-800-962-9888 © 2011 Covidien. Made in Canada. Manufactured for Covidien IIc. 15 Hampshire Street, Mansfield, MA 02048 USA. HP103228



Kendall™

Antifungal Cream

Relieves itching and discomfort associated with fungal infections. Treats most athlete's foot, jock itch, and ringworm. Contains jojoba oil and vitamin E.

REF 61074

4 FL OZ (118 mL)

KENDALL ANTIFUNGAL

miconazole nitrate cream

Product Information

Product T ype	HUMAN OTC DRUG		Item Co	Item Code (Source) ND		DC:28851-692	
Route of Administrati	on	n TOPICAL					
Active Ingredient/	Active Moie	ety					
Ingredient Name Basis of Strengt						Strength	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M) MICONAZOLE NITRAT						2 g in 100 g	
Inactive Ingredien	its						
Ingredient Name						Strength	
Water (UNII: 059QF0KO0R)							
MINERAL OIL (UNII: T5	GL8T28FGP)						
PROPYLENE GLYCOL	(UNII: 6DC9Q1	l67V3)					
SORBITAN MONOSTE	ARATE (UNII: 1	NVZ4I0H58X)					
CETYL ALCOHOL (UN	II: 936JST6JCN	1)					
ISOPROPYL PALMITA	TE (UNII: 8CRO	Q2TH63M)					
SODIUM LACTATE (UN	NII: TU7HW0W0	QT)					
JOJOBAOIL (UNII: 724	GKU717M)						
POLYSORBATE 60 (UI	NII: CAL22UVI4	M)					
VITAMIN A PALMITAT	E (UNII: 1D1K0	N0VVC)					
DIMETHICONE (UNII: 9	2RU3N3Y1O)						
SHEA BUTTER (UNII: K							
		E (350000 MW) (UNII: '	T7SWE4S2TT)				
METHYLPARABEN (UN	· · · · · · · · · · · · · · · · · · ·)					
1-DECENE (UNII: 704U4							
PROPYLPARABEN (UN							
DIAZOLIDINYL UREA		PW4)					
XANTHAN GUM (UNII: 7	,						
ALPHA-TOCOPHEROI	ACETATE (UI	NII: 9E8X80D2L0)					
Packaging							
# Item Code		age Description	Marketing	g Start Date	Marketing	End Date	
1 NDC:28851-692-01	118 g in 1	TUBE					
Marketing Info	rmation						
-							
Marketing Category	Applicatio	n Number or Monogra	anh Citation	Marketing Star	t Date – Market	ing End Date	