SELAN ANTIFUNGAL- selan antifungal cream Trividia Manufacturing Solutions, 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.

Selan AntiFungal

Active Ingredients

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- Cures most jock itch (tinea cruris), ringworm (tinea corporis), athlete's foot (tinea pedis) and superficial yeast infections

- Relieves itching, cracking, burning, redness, irritation and discomfort associated with these conditions

Warnings

For external use only

Do not use on children under 2 years old unless directed by a doctor

When using this product avoid contact with the eyes

Stop use and ask a doctor if irritation occurs or if there is no improvement

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

Directions

- Clean affected area and dry thoroughly

- Apply a thin layer over the affected area twice daily (morning and night) for 2 weeks (jock itch) or 4 weeks (athlete's foot & ringworm)

- Supervise children in the use of this product

For athlete's foot *pay special attention to the space between the toes *wear well fitting, ventilated shoes *change shoes and socks at least once daily

If condition persists longer, or if irritiation occurs, consult a doctor. This product is not effective on the scalp or nails.

Other information

store at room temperature

Inactive ingredients:

Dimethicone, emulsifying wax, fragrance, germaben II, lanolin, propylene glycol, water, zinc oxide

Image of 4oz tube

Treat and cure most athlete's foot, ringworm, jock itch & superficial yeast Relieves itching, burning, redness and scaling associated with these con Distributed by: Span-America Medical Systems, Inc. 70 Commerce Center, Greenville, SC 29615		NDC: 0159-2500-04
ditions. Antifu 2% mice a moist	ingal Cream onazole nitrate in ure barrier cream (T. 4 OZ. (113.4g)	

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 SELAN ANTIFUNGAL

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 Product Information

 Product Type
 HUMAN OTC DRUG

 Route of Administration
 TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength Strength

MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE 2 g in 100 g

Inactive	Ingredients
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Ingredient Name	Strength	
WATER (UNII: 059QF0K00R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)		
LANOLIN (UNII: 7EV65EAW6H)		
DIMETHICONE 1000 (UNII: MCU2324216)		
ZINC OXIDE (UNII: SOI2LOH54Z)		
POLAWAX POLYSORBATE (UNII: Q504PL8E0V)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0159-2500- 04	117 g in 1 TUBE; Type 0: Not a Combination Product	11/05/2003	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part333C	11/05/2003	

Labeler - Trividia Manufacturing Solutions, Inc (018927392)

Establishment			
Name	Address	ID/FEI	Business Operations
Trividia Manufacturing Solutions, Inc		018927392	manufacture(0159-2500) , label(0159-2500) , pack(0159- 2500)

Revised: 2/2022

Trividia Manufacturing Solutions, Inc