TOUCHLESS CARE ANTIFUNGAL- touchless care antifungal spray
Crawford Healthcare, 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.

Touchless Care ANTIFUNGAL SPRAY

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Indications

- Treats jock itch, ringworm and athlete's foot
- For the treatment of most superficial skin irritations caused by yeast (Candida albicans). Follow a physician's instructions when treating Candida.

Warnings

Do not use on children under 2 years of age unless directed by a doctor. Not intended for ingestion. Do not use for diaper rash. For external use only. When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation develops
- there is no improvement within 4 weeks for athlete's foot or ringworm or within 2 weeks for jock itch.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center immediately.

Directions

- Cleanse the affected area and allow to dry.
- Shake bottle well before use.
- Spray 4-6 inches from skin twice daily (morning and night) or as directed by a physician. No rub-in is required.
- For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks. If condition persists longer, contact a doctor. This product is not effective on the scalp or nails.

Other Information

Store at 59 ^{o}F - 87 ^{o}F (15 ^{o}C - 30 ^{o}C)

Inactive Ingredients

Cyclomethicone, Dimethicone, Hexamethyldisiloxane, Lanolin, Light Mineral Oil, Microcrystalline Wax, Vitamin A Palmitate, Vitamin D3, White Petrolatum, Zinc Oxide

SPL Unclassified Section

Distributed by: Crawford Healthcare, Inc. Doylestown, PA 18901

Touchless Care is a registered trademark of Crawford Woundcare Ltd.

www.crawfordhealthcare.com/us

1-855-522-2211

Made in the USA

Package Label

Antifungal label

TOUCHLESS CARE ANTIFUNGAL

touchless care antifungal spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69502-001
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	
Ingredient Name	**Strength**
LANOLIN (UNII: 7EV65EAW6H)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
MINERAL OIL (UNII: T5L8T28FGP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
PETROLATUM (UNII: 4T6H12BN9U)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
HEXAMETHYLDISILOXANE (UNII: D7M4659BPU)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69502-001-57	57 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/28/2017	

Labeler - Crawford Healthcare, Inc. (042813710)

Revised: 2/2017 Crawford Healthcare, Inc.