LEADER MEDICATED- miconazole nitrate powder
Cardinal Health 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.

Drug Facts

Active ingredient

Miconozole nitrate2%

Purpose

Antifungal

Uses

for the cure of most athlete's foot, jock itch and ringworm

Warnings

For external use only.

Do not use

on children under 2 years of age unless directed by a doctor

When using this product

do not get into eyes.

Stop use and ask a doctor if

if irritation occurs or there is no improvement within 4 weeks for athlete's foot and ringworm, or 2 weeks for jock itch.

Keep out of reach of children

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

Directions

- clean and dry affected area
- apply a thin layer of the product 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
- for athlete's foot and ringworm, use daily for 4 weeks ; for jock itch, use daily for 2 weeks
- if condition persists, consult a doctor
- this product is not effective on scalp or nails

Other infomation

Product settles during shipment. Package contains full net weight.

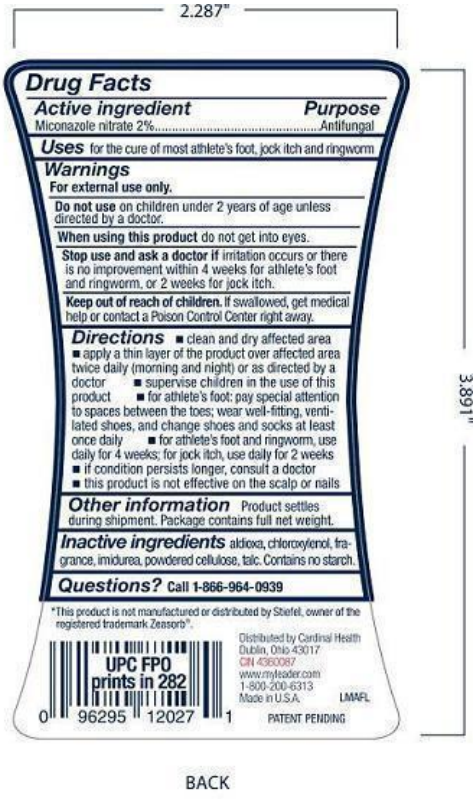
Inactive ingredients

aldioxa, chloroxylenol, fragrance, imidurea, powdered cellulose, talc. Contains no starch

Questions

Call 1-866-964-0939

Box Label



BACK

LABEL SIZE 2.287"W x 3.891"H

Leader Medicated Miconazole Nitrate 2% Powder Spray

LEADER MEDICATED

miconazole nitrate powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-653
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE	1.42 g in 71 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALDIOXA (UNII: 8T66I31YNK)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
IMIDUREA (UNII: M629807ATL)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
TALC (UNII: 7SEV7J4R1U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37205-653-18	71 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/31/2010	

Labeler - Cardinal Health Inc. (097537435)

Revised: 10/2012 Cardinal Health Inc.