MICONAZOLE NITRATE- miconazole nitrate powder
Westminster Pharmaceuticals, LLC

Miconazole Nitrate

Drug Facts

Active ingredient

Miconazole Nitrate 2.0%

Purpose

Antifungul

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- for the treatment of most superficial skin infections caused by yeast (candida albicans)
- relieves most itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

Warnings

- **for external use only**

Do not use

- on children under 2 years of age unless by a doctor
- avoid contact with the eyes
- for athlete's foot and ringworm - if irritation occurs, or if there is no improvement within 4 weeks, discontinue use and consult a doctor
- for jock itch - if irritation occurs, or if there is no improvement within 2 weeks, dicontinue 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 powder 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 athletes foot and ringworm, use daily for 4 weeks

- for jock itch, use daily for 2 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.
- do not use if package is damaged

Inactive ingredients

allantoin, chloroxylenol, fragrance, imidazolidinyl urea, microcrystalline cellulose, tricalcium phosphate, corn starch

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

NDC 69367-399-85

Miconazole

Antifungul Powder
Treatment

Miconazole Nitrate 2%

Botanical Nutrition For
Sensitive Skin

- CHG Compatible
- Paraben Free
- Hypoallergenic

NET WT. 3 OZ (85g)

Westminster
Pharmaceuticals

MICONAZOLE NITRATE

miconazole nitrate powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69367-399
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**
ALLANTOIN (UNII: 344S277G0Z)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
IMIDUREA (UNII: M629807ATL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69367-399-85	85 g in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M005	05/16/2024	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Establishment

Name	Address	ID/FEI	Business Operations
Davion, Inc		079536689	ANALYSIS(69367-399) , MANUFACTURE(69367-399) , PACK(69367-399) , LABEL(69367-399)

Revised: 5/2024 Westminster Pharmaceuticals, LLC