

RELISPRAY ANTIFUNGAL POWDER- miconazole nitrate aerosol, spray
Midas-Care Pharmaceuticals Pvt. Ltd.

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.

Relispray Antifungal Spray Powder

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- effectively treats most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis)
- relieves itching, scaling, burning and discomfort which may accompany these conditions

Warnings

For external use only

Flammable. Do not use while smoking or near heat or flame.

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

When using this product

- avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal
- do not puncture or incinerate. Contents under pressure.
Do not store at temperatures above 120°F

Stop use and ask a doctor if

- irritation occurs
- 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

- wash the affected area and dry thoroughly
- shake can well and apply a thin layer over the affected area twice daily (morning and night)
- 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
- 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 longer, consult a doctor
- this product is not effective on the scalp or nails

Inactive ingredients

aloe vera, aluminum starch octenyl succinate, isopropyl myristate, propellant (isobutane, normal butane, propane), propylene carbonate, SD alcohol 40-B (10% w/w), sorbitan monooleate, stearylalkonium hectorite

Questions or comments?

Call 888-491-1965

PRINCIPAL DISPLAY PANEL - 128 g Can Label

NDC 46063-552-12

Relispray
Antifungal
Spray
Powder

Miconazole Nitrate
2% Antifungal
Spray Powder

Net Wt 4.5 oz (128g)

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**Miconazole Nitrate
 2% Antifungal
 Spray Powder**

Net Wt 4.5 oz (128g)

Drug Facts (continued)

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Mkt'd. By:
 MIDASCARE PHARMACEUTICALS PVT. LTD.
 Lotus Corporate Park, B Wing, 3rd Floor,
 Jay Coach, Graham Firth Compound,
 WE Highway, Goregaon (East),
 Mumbai - 400063, India.

Batch No.:
 Mfg. Date:
 Expiry Date:
 Mfg. Lic. No. AD/009

AT BASE



MADE IN INDIA

RELISPRAY ANTIFUNGAL POWDER

miconazole nitrate aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46063-552
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	Miconazole Nitrate	0.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	

Isopropyl Myristate (UNII: 0RE8K4LNJS)	
LIQUEFIED PETROLEUM GAS (UNII: 5K616HU99V)	
Propylene carbonate (UNII: 8D08K3S51E)	
ALCOHOL (UNII: 3K9958V90M)	
Sorbitan monooleate (UNII: 06XEA2VD56)	
Stearalkonium hectorite (UNII: OLX698AH5P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46063-552-12	128 g in 1 CAN; Type 0: Not a Combination Product	03/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/01/2022	

Labeler - Midas-Care Pharmaceuticals Pvt. Ltd. (862273427)

Revised: 1/2022

Midas-Care Pharmaceuticals Pvt. Ltd.