

ASTONEA MICONAZOLE NITRATE- antifungal powder
ASTONEA LABS PRIVATE LIMITED

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.

Astonea Anti-Fungal Powder Talc

Active Ingredients

Miconazole nitrate 2%

Purpose

Antifungal

Uses

fFor the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) ■Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch or itching, burning feet

Warnings

For external use only.

Do not use

: ■On children under 2 years of age unless directed by a doctor ■For diaper rash

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- Irritation occurs
- There is no improvement within 2 weeks when used for the treatment of jock itch
- There is no improvement within 4 weeks when used for athlete's foot or ringworm

Keep out of reach of children.

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

Directions

- clean the affected area & dry thoroughly
- 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 the toes; wear well-fitting, ventilated shoes, & change shoes & socks at least once daily
- for athlete's foot & 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

- Store at room temperature

Inactive ingredients

Colloidal Anhydrous Silica, Talcum Powder

Questions?

Call 1-866-964-0939

Pincipal Display Panel

ASTONEA

ANTIFUNGAL POWDER

MICONAZOLE NITRATE 2%

*Helps treat foot odor,
athlete's foot
and ringworm*

NET WT.: 3 OZ. (85G)

Drug Facts

Active ingredient	Purpose
Miconazole Nitrate (2% w/w).....	Antifungal

Uses ■ For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) ■ Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch or itching, burning feet

Warnings: For external use only.

Do not use: ■ On children under 2 years of age unless directed by a doctor ■ For diaper rash

Ask a doctor or a pharmacist before use if you are taking: ■ Anti coagulants ■ Warfarin

When using this product avoid contact with eyes

Stop use and ask a doctor if ■ Irritation occurs ■ There is no improvement within 2 weeks when used for the treatment of jock itch ■ There is no improvement within 4 weeks when used for athlete's foot or ringworm

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 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 the 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 longer, consult a doctor ■ This product is not effective on the scalp or nails

Other information: Store at room temperature

Inactive ingredients:

Colloidal Anhydrous Silica, Talcum Powder

LOT



Manufactured by:

Astonea Labs Private Limited

Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula,
Haryana, India - 134204

Made in India

HR/DRUGS 1105-OSP(H)

ASTONEA MICONAZOLE NITRATE

antifungal powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-165
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-165-03	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/19/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022

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