

**MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL- miconazole nitrate cream  
ASTONEA LABS PRIVATE LIMITED**

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**MICONAZOLE Nitrate 2% Cream ANTIFUNGAL**

***Drug Facts***

***Active ingredient***

Miconazole Nitrate 2% w/w

***Purpose***

Anti-Fungal

***Uses***

- For the treatment and prevention of most athlete's foot (tinea pedis), jock itch (tinea crurus), and ringworm (tinea capitis)
- relieves itching, scaling, cracking, burning and discomfort associated with these conditions.

***Warnings***

For external use only

on children under 2 years of age unless directed by Doctor

***When using this product***

Avoid contact with eyes

***Stop use and ask a doctor if***

irritation occurs

there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)

***Keep out of reach of children***

In case of accidental ingestion contact a physician or Poison Control Center right away and discomfort which accompany these conditions

***Directions***

Clean the affected area and dry thoroughly • Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a healthcare professional • Supervise children in the use of this product.

**For athlete's foot:** • Use daily for 4 weeks. If condition persists, consult a healthcare professional. • Pay special attention to the spaces between the toes • Wear well fitting, ventilated shoes • Change socks atleast once daily.

**For ringworm:** Use daily for 4 weeks. If condition persists, consult a healthcare professional.

**For jock itch:** Use daily for 2 weeks. If condition persists longer, consult a healthcare professional.

This product is not effective on the scalp or nails.

### ***Other Information***

- Store at 15° - 30° c (59° - 86° f)

Caprylic/capric triglyceride, Cetereath-20, Cetearyl Alcohol, Chlorocresol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidazolidinyl Urea, PEG-100 Stearate, PEG-40 Castor Oil, Petrolatum, Propylene Glycol, Sodium Cetearyl Sulfate, Stearic Acid, Water, Xanthum Gum

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Miconazole Nitrate 2% w/w .....	Antifungal
<b>Uses</b> ■ For the treatment and prevention of most: ■ Athlete's foot ■ Jock itch ■ Ringworm ■ Relieves itching, scaling, cracking, and discomfort associated with these conditions	
<b>Warnings</b> ■ For external use only	
<b>Do not use</b> on children under 2 years of age unless directed by doctor	
<b>When using this product</b> ■ Avoid contact with eyes	
<b>Stop use and ask a doctor if</b> ■ Irritation occurs ■ There is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)	
<b>Keep out of reach of children.</b> In case of accidental ingestion contact a physician or Poison Control Center right away and discomfort which accompany these conditions	
<b>Directions</b> ■ Cleanse affected area and dry thoroughly. ■ Apply a thin layer to affected area twice daily or as directed by a physician ■ Supervise children in the use of this product ■ For athlete's foot and ringworm use daily for 4 weeks; for jock itch use daily for 2 weeks ■ For athlete's foot pay special attention to space between the toes; wear well-fitting ■ Ventilated shoes and change shoes and socks at least once daily. This product is not effective on the scalp or nails	
<b>Other Information</b> ■ Store at room temperature 15°-30°C (59°-86°F)	
<b>Inactive Ingredients</b> Caprylic/Capric Triglyceride, Cetearth-20, Cetearyl Alcohol, Chlorocresol, Dimethicone, Disodium EDTA, Glyceryl Stearate, Imidazolidinyl Urea, PEG-100 Stearate, PEG-40 Castor Oil, Petrolatum, Propylene Glycol, Sodium Cetearyl Sulfate, Stearic Acid, Water, Xanthan Gum	

Patient Name:  
Room #:

# ASTONEA

## Miconazole Nitrate 2%



SOOTHES AND PROMOTES HEALING  
CURES JOCK ITCH & RING WORM

4 Oz. (113g)

**Manufactured by:**  
**Astonea Labs Private Limited**  
**Village Haripur, Tehsil Raipurani,**  
**Near Mouli Police Station,**  
**Panchkula, Haryana,**  
**India - 134204**

HR/DRUGS 1105-OSP(H)

### MICONAZOLE NITRATE 2% CREAM ANTIFUNGAL

miconazole nitrate cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-041	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)		MICONAZOLE NITRATE	2 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
PEG-100 STEARATE (UNII: YD01N1999R)				
WATER (UNII: 059QF0KO0R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
XANTHAN GUM (UNII: TTV12P4NEE)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
CHLOROCRESOL (UNII: 36W53O7109)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)				
IMIDUREA (UNII: M629807ATL)				
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)				
PETROLATUM (UNII: 4T6H12BN9U)				
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77338-041-25	113 g in 1 TUBE; Type 0: Not a Combination Product	08/16/2022	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M005		03/22/2016	

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

### Establishment

Name	Address	ID/FEI	Business Operations
ASTONEA LABS PRIVATE LIMITED		878533295	manufacture(77338-041)

