

MEDLINE- miconazole nitrate cream
Medline Industries, LP

147 Remedy Clinical Antifungal Cream

Active ingredient

Miconazole nitrate 2.0% w/v

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) or ringworm (tinea corporis)
- relieves 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 directed by doctor

When using this product

- avoid contact with the eyes

Stop use and ask a doctor

- if irritation occurs
- there is no improvement within 4 weeks for athlete's foot and ringworm
- there is no improvement within 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 the affected area and dry thoroughly
- apply a thin layer over affected area twice daily or as directed by a physician
- supervise use by children
- 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 four weeks; for jock itch, use daily for

two weeks

- if condition persists longer, consult a doctor
- this product is not effective on scalp or nails

Other information

- protect from freezing
- avoid excessive heat

Inactive ingredients

acrylamide/ammonium acrylate copolymer, aloe barbadensis leaf juice, apricot kernel oil, PEG-6 esters, ascorbic acid, ascorbyl palmitate, cetyl dimethicone, cholecalciferol, citric acid, citrus aurantium dulcis (orange) peel oil, citrus grandis (grapefruit) peel oil, citrus tangerina (tangerine) peel oil, diazolidinyl urea, ethyl vanillin, glycine, glycine soja (soybean) oil, glycol stearate, hydroxytyrosol, l-proline, l-aurine, methylparaben, methylsulfonylmethane, n-acetyl-l-cysteine, niacinamide, olea europaea (olive) fruit oil, olea europaea (olive) leaf extract, PEG-6 stearate, PEG-8, PEG-32 stearate, polyisobutene, polysorbate 20, propanediol, propylene glycol, propylparaben, pyridoxine HCL, retinyl palmitate, silica, tocopherol, triethanolamine, vanillin, water, zea mays oil

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA with domestic and foreign materials

www.medline.com

1-800-MEDLINE (633-5463)

REF: MSC092604

V1 RL22WAS

Package Label



Drug Facts

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CLINICAL

TREAT

Antifungal Cream
2% Miconazole Nitrate

For skin with a
fungal infection



CHG Compatible
Hypoallergenic

Scented



REF MSC092604

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4 FL OZ (118 mL)

MEDLINE

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-147
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
TOCOPHEROL (UNII: ROZB2556P8)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PROPANEDIOL (UNII: 5965N8W85T)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
SOYBEAN OIL (UNII: 241ATL177A)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ACETYLCYSTEINE (UNII: WYQ7N0BPHYC)	
PEG-32 STEARATE (UNII: 33GX5WQC0M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROLINE (UNII: 9DLQ4CIU6V)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TAURINE (UNII: 1EQV5MLY3D)	
ORANGE OIL (UNII: AKN3KSD11B)	
MANDARIN OIL (UNII: NJO720F72R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HYDROXYTYROSOL (UNII: QEU0NE4O90)	
CORN OIL (UNII: 8470G57WFM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-147-44	118 mL in 1 TUBE; Type 0: Not a Combination Product	08/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/01/2023	

Labeler - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)

Revised: 12/2023

Medline Industries, LP