REMEDY ANTIFUNGAL WITH OLIVAMINE- miconazole nitrate cream Medline Industries, LP

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.

162 Antifungal

Active ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Use

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- For the treatment of superficial skin infections caused by yeast (Candida albicans)
- 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 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, discontinue 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 layer of cream 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 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

• 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-taurine, 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, water.

Medline Remedy is a registered trademark of Medline Industries, Inc. Olivamine is a registered trademark of McCord Research, Inc. Manufactured in USA for Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60093 USA.

www.medline.com 1-800-MEDLINE RJ18WAR

Principal Display Panel - Remedy

Remedy is a well-balanced meal for skin cells. With nourishing Olivamine®: A blend of potent antioxidants, amino acids, vitamins and MSM.

Drug Facts

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Medine Penedy is a registered trademark of Medine Industries, Inc. Clivamine is a registered trademark of McCord Pesearch, Inc. Manusatured in USV for Medine Industries, Inc., Three Lakes Drive, Northfield, IL 60033 USV. www.medine.com + 600 MEDUINE RJ18 WAR





OLIVAMINE



PREVENTION ABOVE ALL

MEDLINE

NDC 53329-162-04

REMEDY°

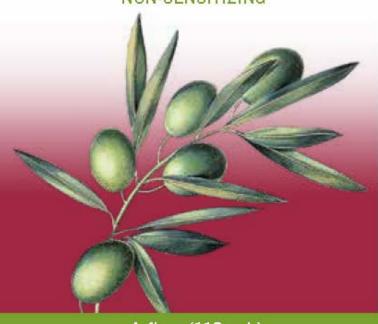
WITH OLIVAMINE®

ANTIFUNGAL CREAM

TARGETED TREATMENT

Nourishes and helps relieve fungal symptoms of itching, burning and irritation.

NON-ALLERGENIC NON-SENSITIZING



4 fl oz (118 mL)

REMEDY ANTIFUNGAL WITH OLIVAMINE

miconazole nitrate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53329-162

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
TROLAMINE (UNII: 903K93S3TK)	
PROPANEDIOL (UNII: 5965N8W85T)	
VANILLIN (UNII: CHI530446X)	
WATER (UNII: 059QF0KO0R)	
CORN OIL (UNII: 8470G57WFM)	
TAURINE (UNII: 1EQV5MLY3D)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
MANDARIN OIL (UNII: NJO720F72R)	
HYDROXYTYROSOL (UNII: QEU0NE4O90)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
ORANGE OIL (UNII: AKN3KSD11B)	
PROLINE (UNII: 9DLQ4CIU6V)	
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
PEG-32 STEARATE (UNII: 33GX5WQC0M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCINE (UNII: TE7660XO1C)	
SOYBEAN OIL (UNII: 241ATL177A)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: ROZB2556P8)	

Packaging	ackaging				
# Item Cod	le	Package Description	Marketing Start Date	Marketing End Date	
NDC:53329-1	.62- 113 g Produ	in 1 TUBE; Type 0: Not a Combination ct	01/01/2007	07/26/2024	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	01/01/2007	07/26/2024			

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 10/2022 Medline Industries, LP