GENRX DAILY DEFENSE ANTIFUNGAL- miconazole nitrate cream
PureTek Corporation

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.

Active ingredient

Miconazole Nitrate 2.0%

Purpose

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

Warnings

For external use only

Do not use on

children under 2 years of age unless directed by a doctor

When using this product

avoid contact with eyes

Stop use and ask a doctor if

■ for athlete's foot and ringworm - irritation occurs or there is no improvement within 4 weeks
■ for jock itch - irritation occurs or there is no improvement within 2 weeks

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 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, 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

■ protect from freezing ■ avoid excessive heat

Inactive ingredients

Aleurites moluccana seed oil, butylene glycol, caprylyl glycol, *Carthamus tinctorius* (safflower) seed oil, cetyl alcohol, cetyl phosphate, chlorphenesin, dimethicone, dimethicone crosspolymer, disodium EDTA, fragrance, glycerin, glyceryl stearate, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B_5), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B_3), pyridoxine HCl (vitamin B_6), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], PEG-100 stearate, pentylene glycol, phenoxyethanol, purified water, sodium hyaluronate, sodium hydroxide, stearyl alcohol.

Daily Defense Antifungal Cream with GenRx Complex™ (4 oz tube label)

Room No.

Name

Drug Facts

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PureTek Guarantee: Every PureTek product is manufactured and tested to meet or exceed all USP standards.

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LATEX-FREE

Manufactured in the USA by:
PureTek Corporation, San Fernando, CA 91340 • 877-921-7873
For more info, visit: www.genrxwoundcare.com
LIST NO. 74608 AAA Rev: 240278-00

NDC 59088-746-08

Gen+Rx™

WOUND CARE
Hypo-Allergenic

Daily Defense Antifungal Cream

with
GenRx Complex™

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

- Physician Tested
- Non-sensitizing
- Promotes Healing
- Clinically Proven
- Helps Skin Cell Renewal
- Paraben Free

4 fl oz / 118 mL

GENRX DAILY DEFENSE ANTIFUNGAL

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-746
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**
KUKUI NUT OIL (UNII: TP11QR7B8R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GINGER (UNII: C5529G5JPQ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-746-08	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/08/2013	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-746) , pack(59088-746) , label(59088-746)

Revised: 1/2013

PureTek Corporation