

CLOTRIMAZOLE- clotrimazole cream

Promex, LLC

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.

Drug Facts

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- Cures most athlete's foot, jock itch, and ringworm
- Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

Warnings

For external use only

Do not use

- on children under 2 years of age except under the advice and supervision of a 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) or 2 weeks (for jock itch) Do not use for diaper rash

Keep out of reach of children

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

Directions

- Wash 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 a day
- For athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- If conditions persist longer, ask a doctor
- This product is not effective on the scalp or nails

Other information

- store between 2° and 30°C (36° and 86°F)

Inactive ingredients

Benzyl alcohol, Carbomer940, Cetyl alcohol, Glycerin, Glyceryl monostearate, Light liquid paraffin, Purified water, Stearic acid and Trolamine

Clotrimazole

KNEZTENG[®] CREAM

-Relieves itching, burning, cracking and scaling
-Alivia la picazón, ardor, agrietamiento y exfoliación



ProMEX[®]

KNEZTENG[®] CREAM

-Relieves itching, burning, cracking and scaling
-Alivia la picazón, ardor, agrietamiento y exfoliación



ProMEX[®]

28.35 g. (1 oz)



LOT & EXP.

KNEZTENG[®]

KNEZTENG[®]

<p>Drug Facts (continued)</p> <p>Inactive ingredients benzyl alcohol, carbomer 940, cetyl alcohol, glycerin, glyceryl monostearate, light liquid paraffin, purified water, stearyl acid, and trielaine</p> <p>Pro-Mex[®] Miami, FL 33179 1 (305) 653-2700</p> <p>Questions Comments?</p>	<p>Información del Medicamento (continuación)</p> <p>Ingredientes inactivos alcohol bencílico, carbómero 940, alcohol cetílico, glicerina, monoestearato de glicerilo, parafina líquida ligera, agua</p> <p>Información adicional ■ Almacenar entre 2° - 30° C (36° - 86° F)</p>
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<p>Drug Facts</p> <p>Active ingredients (in each gram) Purpose Clotrimazole 1%.....Antifungal</p>	<p>Información del Medicamento</p> <p>Ingredientes activos (por cada gramo) Propósito Clotrimazol 1%.....Antihongos</p>
<p>Uses</p> <p>■ Cures most athlete's foot, jock itch, and ringworm ■ Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions</p> <p>Warnings Do not use on children under 2 years of age except under the advice and supervision of a doctor</p> <p>For external use only</p> <p>When using this product avoid contact with the eyes</p> <p>Stop use and ask a doctor if</p> <p>■ Irritation occurs ■ There is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)</p> <p>■ Do not use for diaper rash</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>■ Wash 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 a day ■ For athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks ■ If conditions persist longer, ask a doctor ■ This product is not effective on the scalp or nails</p> <p>Other information</p> <p>■ Store between 2° and 30° C (36° and 86° F)</p>	<p>Indicaciones</p> <p>■ Lave el área afectada y seque completamente ■ Aplicar una capa fina sobre la zona afectada dos veces al día (mañana y noche) o como lo indique un médico ■ Supervisar los niños en el uso de este producto ■ Para el pie de atleta, prestar especial atención a los espacios entre el dedos de los pies, use zapatos cómodos y con ventilación, cambiar los zapatos y los calcetines por lo menos una vez al día ■ Para el pie de atleta y dermatofitosis utilizar diariamente durante 4 semanas para la tija inguinal utilizar diariamente durante 2 semanas ■ Si las condiciones persisten más tiempo, consulte a un médico</p> <p>■ Este producto no es eficaz en el cuero cabelludo o las uñas</p>
<p>Mantener fuera del alcance de los niños. En caso de que sea ingerido, obtenga ayuda médica o contacte un Centro de Control de Intoxicación inmediatamente.</p>	<p>Indicaciones</p> <p>■ Este producto no es eficaz en el cuero cabelludo o las uñas</p>

Made in Korea / Fabricado en Corea

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0022-1	1 in 1 BOX		
1		28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/04/2013	

Labeler - Promex, LLC (789974388)

Revised: 12/2013

Promex, LLC