WINCO FOODS ANTIFUNGAL- clotrimazole cream Winco Foods 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.

Winco Antifungal Clotrimazole Cream 1 oz 24196 ZDP 2021

Active ingredient Purpose

Clotrimazole 1%......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)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- 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, ask a doctor
- this product is not effective on the scalp or nails

Other information

• store at room temperature 20-25°C (68-77°F)

Inactive ignredients

cetostearly alcohol, ethylparaben, glycerin, light mineral oil, propylene glycol, purified

water, sodium sulfite, steareth-20, stearic acid

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Distributed by:

Winco Foods, LLC Boise, ID 83704 Made in China



clotrimazole cream

Product Information

HUMAN OTC DRUG NDC:67091-196 **Product Type Item Code (Source)**

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) CLOTRIMAZOLE

10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM SULFITE (UNII: VTK01UQK3G)	
ETHYLPARABEN (UNII: 14255EXE39)	
STEARETH-20 (UNII: LOQ8IK9E08)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
WATER (UNII: 059QF0KO0R)	

Packaging Marketing Start Marketing End Item Code Package Description Date Date 1 NDC:67091-196-1 in 1 CARTON 05/20/2021 28

28 g in 1 TUBE; Type 0: Not a Combination 1 Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	05/20/2021		

Labeler - Winco Foods LLC (056098817)

Revised: 1/2022 Winco Foods LLC