PRIVATE LABEL ANTIFUNGAL BARRIER CREAM- miconazole nitrate antifungal cream cream
Swiss-American CDMO, LLC

Private Label Antifungal Barrier Cream

Warnings

For external use only. Not intended for ingestion. Do not use on children under 2 year of age unless directed by a doctor. Avoid contact with the eyes. For the treatment of athlete's foot and ringworm. If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor. For the prevention of athlete's foot: if irritation occurs, discontinue use and consult a doctor. Do not use for diaper rash. If swallowed, get medical help or contact a Poison Control Center right away.

Active Ingredients

Miconazole Nitrate 2.0%

Indications & Uses

Proven clinically effective in the treatment of most athlete's foot (tinea pedia), jock itch (tinea cruris) and ringworm (tinea corporis). For the treatment of superficial skin infections caused by yeast (candida albicans). For effective relief of redness, irritation, scaling, itching, discomfort and burning.

Directions

Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily as directed by a doctor or health care professional. 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.

Keep out of reach of children

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Inactive ingredients

Allantoin, bees wax, cetyl dimethicone, cetyl PEG/PPG-10/1 dimethicone, dimethicone, ethylhexylglycerin, fragrance, hydrogenated castor oil, isopropyl palmitate, petrolatum, phenoxyethanol, purified water, sodium chloride, zinc oxide

Questions?

Call toll free 1-866-416-2366

Purpose

Antifungal

Labeling

PRIVATE LABEL ANTIFUNGAL BARRIER CREAM

miconazole nitrate antifungal cream cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICONE 1000 (UNII: MCU2324216)	
BEESWAX (UNII: 2ZA36H0S2V)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0046-1	85 g in 1 TUBE; Type 0: Not a Combination Product	05/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/09/2025	

Labeler - Swiss-American CDMO, LLC (080170933)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(60232-0046)

Revised: 5/2025 Swiss-American CDMO, LLC