DERMOSCRIBE DIAPER- clioquinol, zinc oxide ointment DERMOSCRIBE PTY LTD

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 INGREDIENTS:

ZINC OXIDE 15% CLIOQUINOL 1%

PURPOSE

ANTIFUNGAL ANTIBACTERIAL

USES

A SAFE, EFFECTIVE TREATMENT FOR THE SIGNS AND SYMPTOMS OF DIAPER RASH. REDUCES INFLAMMATION AND HELPS PREVENT BACTERIAL INFECTIONS.

WARNINGS

WARNINGS

FOR EXTERNAL USE ONLY

IF BABY'S CONDITION FAILS TO IMPROVE, SEE YOUR DOCTOR.

DO NOT USE IF BABY IS ALLERGIC TO ANY OF THE INGREDIENTS.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS:

WASH HANDS WITH SOAP AND WATER BEFORE AND AFTER USE. USING FINGERS, GENTLY APPLY OINTMENT OVER AFFECTED AREA. FOLLOWING AN INITIAL FLARE-UP, APPLY OINTMENT AFTER EVERY DIAPER CHANGE. ONCE THE RASH HAS SETTLED, APPLY TWO OR THREE TIMES DAILY, AS REQUIRED. ASK YOUR HEALTHCARE PROFESSIONAL IF YOU ARE UNSURE OF THE CORRECT DOSAGE FOR YOUR BABY.

INACTIVE INGREDIENTS

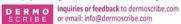
OLIVE OIL 17.5%, BORIC ACID 0.25%, MINERAL OIL, PETROLATUM, BEESWAX, GLYCERYL STEARATE, PARAFFIN WAX, VITAMIN E, LANOLIN, POTASSIUM SORBATE, SODIUM BENZOATE.

STORE AT ROOM TEMPERATURE IN A DRY PLACE, AWAY FROM DIRECT SUNLIGHT AND OUT OF REACH OF CHILDREN. MAY NOT BE AS EFFECTIVE AFTER EXPIRY DATE.

DERMOSCRIBE MEDICATED DIAPER OINTMENT is a safe, effective treatment for the signs and symptoms of Diaper Rash. If baby's condition fails to improve, see your doctor. Ingredients include clioquinol, a topical anti-fungal agent and zinc oxide, which reduces inflammation and helps prevent bacterial infections.

Manufactured in the USA to Dermoscribe's specific formula in an FDA Registered GMP-compliant facility.

Store at room temperature in a dry place, away from direct sunlight and out of reach of children. May not be as effective after expiry date. Registered under FDA's National Drug Code.





DERMOSCRIBE DIAPER OINTMENT is a medicated ointment used to help relieve the symptoms and signs of Diaper Rash. Directions: Wash hands with soap and water before and after use. Using fingers, gently apply ointment over affected area. Following an initial flare-up, apply ointment after each diaper change. Once the rash has settled, apply two or three times daily, as required. Ask your healthcare professional if you are unsure of the correct dosage for your baby.

Contains: Zinc Oxide 15%, Clioquinol 1%, Olive Oil 17.5%, Boric Acid 0.25%. Also contains Mineral Oil, Petrolatum, Beeswax, Glyceryl Sterate, Parrafin Wax, Vitamin E, Lanolin, Potassium Sorbate, Sodium Benzoate.

DO NOT USE if baby is allergic to any of the ingredients.

DERMOSCRIBE DIAPER

clioquinol, zinc oxide ointment

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69683-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength CLIOQUINOL (UNII: 7BHQ856EJ5) (CLIOQUINOL - UNII:7BHQ856EJ5) CLIOQUINOL 1 g in 100 g ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION 15 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
OLIVE OIL (UNII: 6UYK2W1W1E)			
BORIC ACID (UNII: R57ZHV85D4)			
MINERAL OIL (UNII: T5L8T28FGP)			
PETROLATUM (UNII: 4T6H12BN9U)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
LANOLIN (UNII: 7EV65EAW6H)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69683-102-11	100 g in 1 JAR; Type 0: Not a Combination Product	03/23/2015	

Marketing	Information
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Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

OTC monograph not final	part348	03/23/2015	

Labeler - DERMOSCRIBE PTY LTD (742164734)

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