

DIAPERRASH OINTMENT- zinc oxide ointment
Pharmacy Value Alliance, 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.

Diaper Rash Ointment

Drug Facts

Active Ingredient

Zinc Oxide 40%

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash and helps protect skin from wetness

Keep out of the reach of children.

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

Warnings

For External Use Only

When using this product

- Avoid contact with eyes

Directions

- Change wet and soiled diapers promptly
- Cleanse the diaper area and allow to dry
- Apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Stop use and ask a doctor if

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again with a few days

Other Information:

- Store at controlled room temperature 20° - 25°C (68° - 77°F)

Inactive Ingredients

BHA, Cod liver oil (high in vitamin A and D), Frangrance, Lanolin, Mineral Oil, Methylparaben, Petrolatum, Purified water, Talc, Tartrazine yellow #4 (FD and C yellow #4)

Helps treat and prevent diaper rash. Protects skin. Relieves Chafing. Promotes Healing

Distributed by:

Pharmacy Value Alliance, LLC.

407 East Lancaster Avenue, Wayne, PA. 19087 USA

www.emersongroup.com

Packaging



DIAPERRASHOINTMENT

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-128	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	40 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
PETROLATUM (UNII: 4T6H12BN9U)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
MINERAL OIL (UNII: T5L8T28FGP)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-128-20	113 g in 1 TUBE; Type 0: Not a Combination Product	02/28/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		08/22/2016	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)