

DIAPER RASH- zinc oxide cream

DolGenCorp, 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 ingredients

Active ingredient

Zinc oxide 13%

Purpose

Purpose

Skin protectant

Uses

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warnings

Warnings

For external use only

When using this product

When using this product

- do not get into eyes

Stop use

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area

- 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.

other information

Other information 2.2ex0em2.2ex0emstore between 20° and 25°C (68° and 77° F)

Inactive ingredients

Inactive ingredients aloe barbadensis leaf juice, beeswax, dimethicone, ethylhexylglycerin, fragrance, magnesium sulfate, microcrystalline wax, mineral oil, PEG-30 dipolyhydroxystearate, petrolatum, phenoxyethanol, potassium hydroxide, sorbitan sesquioleate, tocoperyl acetate, water

Questions

Questions? Call 1-888-309-9030

Disclaimer

This product is not manufactured or distributed by Johnson + Johnson Consumer Products Company, distributor of Desitin

Made in the U.S.A. of U.S. and imported parts

Adverse reactions

DISTRIBUTED BY

DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Principal display panel

DG baby

Diaper

Rash

Cream

Skin Protectant

Zinc Oxide 13%

- Goes on smoothly
- Helps heal, soothe and prevent diaper rash

Compare to Desitin

NET WT 4 OZ (113 g)



DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-148
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.113 kg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

YELLOW WAX (UNII: 2ZA36H0S2V)
DIMETHICONE (UNII: 92RU3N3Y1O)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
MAGNESIUM SULFATE (UNII: DE08037SAB)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
MINERAL OIL (UNII: T5L8T28FGP)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
PETROLATUM (UNII: 4T6H12BN9U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0K00R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-148-26	1 in 1 CARTON		
1		113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	07/29/2011	

Labeler - DolGenCorp, LLC (068331990)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55910-148)