CVS HEALTH DIAPER RASH- zinc oxide cream NATURAL ESSENTIALS, INC.

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 ingredient

Zinc Oxide (13%)

Purpose

Skin Protectant

Uses

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

Warnings

For external use only

When using this product

do not get into eyes.

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.

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

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

- store at 20° to 25°C (68° to 77°F)
- protect from freezing
- may stain clothing

Inactive ingredients

Water, Mineral Oil (Paraffinium Liquidum), Petrolatum, Beeswax, Sorbitan Sesquioleate, Glycerin, Microcrystalline Wax, Dimethicone, Phenoxyethanol, Ethylhexylglycerin, Magnesium Sulfate, Aloe

Barbadensis Leaf Extract, Tocopheryl Acetate, Potassium Hydroxide.

Principal Display Panel – Box Label

CVS

Health_®

Compare to the active ingredient in Desitin[®] Daily Defense Diaper Rash Cream*

Cream

Diaper Rash Cream

ZINC OXIDE 13%

Skin protectant

Daily use for diaper rash

Fast acting

Paraben Free

Fragrance free

NET WT 4 OZ (113 g)



Principal Display Panel – Tube Label

CVS

Health_®

Cream

Diaper Rash

Cream

ZINC OXIDE 13%

Skin protectant

Daily use for diaper rash

Fast acting

Paraben Free

Fragrance free

NET WT 4 OZ (113 g)



Cream

Diaper Rash Cream

ZINC OXIDE 13% Skin protectant

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- Fast acting
- Paraben free
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Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 1-800-SHOP CVS

CVS Quality

CVS HEALTH DIAPER RASH

zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66902-449

Active	Ingredient/Active	Moiety
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Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Cation - UNII:13S1S8SF37)	Zinc Cation	14.7 g in 113 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
MINERAL OIL (UNII: T5L8T28FGP)			
PETROLATUM (UNII: 4T6H12BN9U)			
WHITE WAX (UNII: 7G1J5DA97F)			
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)			
GLYCERIN (UNII: PDC6A3C0OX)			
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
PHENO XYETHANO L (UNII: HIE492ZZ3T)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
.ALPHATO COPHEROL (UNII: H4N855PNZ1)			
POTASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)			

]	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-449-04	1 in 1 BOX	04/01/2020	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2020	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment			
Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-449)