

CURETECH SKIN PROTECTANT- zinc oxide ointment
CURETECH SKINCARE

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.

Curetech Gard

Drug Facts

Active ingredient

Zinc Oxide (1.8% w/w)

Purpose

Skin Protectant

Uses:

- Helps treat and prevent diaper rash, incontinence or exposure to feces and urine
- Protects Skin against irritation due to such rash and
- Helps protect skin from exposure to wetness

Warnings:

☐ **For external use only**

When using this product

- Avoid contact with eyes
- If eye contact occurs, flush with water

Stop use and ask a doctor if:

- Condition worsens or does not improve within seven days

Keep out of reach of children

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

Directions:

- Change wet or soiled diapers promptly
- Clean diaper area with a mild cleanser, paying special attention to the perinium, buttocks, lower abdomen and inner thighs
- Allow to dry
- Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged

Other information:

- Store at room temperature 15° - 30°C (59° - 86°F)
- Avoid excessive heat

Inactive ingredients:

~
Aloe Barbadensis Gel, Alpha-Tocopherol(Vitamin E), Cetostearyl Alcohol, Cholecalciferol (Vitamin D), FD&C Yellow No. 5, FD&C Yellow No. 6, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Lavender, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Benzoate, Sodium Laureth-3 Sulfate, Vitamin A Palmitate, Water.

Package Labeling:

Curetech

VITAMIN
ENRICHED

SKIN PROTECTANT

Specially
formulated for
gentle skin



ALOE VERA
VITAMIN A · VITAMIN D
VITAMIN E · ZINC OXIDE

4 FL. OZ. (113g)



Drug Facts

Active ingredient	Purpose
Zinc Oxide 1.8%	Skin Protectant

Uses ■ Helps treat and prevent rash associated with diaper rash, incontinence or exposure to feces and urine
■ Protects skin against irritation due to such rash and
■ Helps protect skin from exposure to wetness

Warnings

FOR EXTERNAL USE ONLY

When using this product ■ Avoid contact with eyes
■ If eye contact occurs, flush with water

Stop use and ask a doctor if

■ condition worsens or doesn't improve within seven days

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

Directions

- Change wet or soiled diapers promptly
- Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs
- Allow area to dry
- Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged

Other information

- Store at room temperature 15° - 30°C (59° - 86°F)
- Avoid excessive heat

Inactive Ingredients Aloe Barbadensis Gel, Alpha Tocopherol (Vitamin E), Cetostearyl Alcohol, Cholecalciferol (Vitamin D), FD&C Yellow No.5, FD&C Yellow No.6, Glycerin, Glyceryl Mono Stearate, Isopropyl Myristate, Lanolin, Lavender, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Benzoate, Sodium Laureth-3 Sulfate, Stearic Acid, Vitamin A Palmitate, Water

Curetech

Manufactured by:
Curetech Skincare
Plot No. 32,33,34, Phase- IV
Bhatoli Kalan, Baddi Solan,
Himachal Pradesh, India
Made In India

CURETECH SKIN PROTECTANT

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73622-0500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73622-0500-4	113 g in 1 TUBE; Type 0: Not a Combination Product	11/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/21/2019	

Labeler - CURETECH SKINCARE (677682180)