

## **DR. SMARTH SHIELD- zinc oxide ointment**

### **Crystal Curam**

*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.*

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### **Dr. Smarth Shield**

#### ***Active Ingredient***

Zinc Oxide 3.8%

#### ***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 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 and 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 with each diaper change, especially at bedtime or anytime when exposure to soiled diapers may be prolonged

#### ***Inactive ingredients***

Aloe Barbadensis Gel, Alpha Tocopherol (Vitamin E), Cholecalciferol (Vitamin D), Chloroxylenol, Cetostearyl Alcohol, Corn Oil, Ethylhexylglycerin, Fragrance, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Microcrystalline wax, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Borate, Sodium Lauryl Sulfate, Stearic Acid, Vitamin A Palmitate, Water

## Package Label



# Crystal

## Skin Protectant Ointment

For the Treatment or Prevention  
of Rash Associated with Diaper Use,  
Incontinence or Exposure to Feces and Urine

Forms Protective Barrier  
to Seal out Wetness

Zinc Oxide

Vitamin A, D & E

Reorder #: 500 3.5 OZ. (100 GRAMS)

# Crystal

## Skin Protectant Ointment

### Drug Facts

Active ingredient	Purpose
Zinc Oxide 3.8%.....	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

**Inactive Ingredients** Aloe Barbadosis Gel, Alpha Tocopherol (Vitamin E), Cholecalciferol (Vitamin D), Chloroxylenol, Cetostearyl Alcohol, Corn Oil, Ethylhexylglycerin, Fragrance, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Microcrystalline Wax, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Borate, Sodium Lauryl Sulfate, Stearic Acid, Vitamin A Palmitate, Water

Manufactured by: -  
 CRYSTAL CURAM  
 H. No. 194 Globe Complex Bldg.  
 No. H1 Gala No. 678 Dapoda Road,  
 Postal Code - 421302, Mumbai  
 Made in India

CS-80200

## DR. SMARTH SHIELD

zinc oxide ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72886-8020
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.8 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CORN OIL (UNII: 8470G57WFM)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72886-8020-4	452 g in 1 JAR; Type 0: Not a Combination Product	02/01/2019	
2	NDC:72886-8020-0	100 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2019	

**Labeler** - Crystal Curam (675483147)