SKYLARK- zinc oxide ointment
Skylark CMC

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.

Active ingredient

Zinc Oxide 3.8%

Purpose

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 rightaway

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 anytime when exposure to soiled diapers may be prolonged

Inactive Ingredients

Aloe Barbadensis Gel, Chloroxylenol, Cholecalciferol (Vitamin D3), Zea Mays Oil, Fragrance, Lanolin, Mineral Oil, Paraffin, Phenoxyethanol, Retinyl Palmitate (Vitamin A), Sodium Borate, Tocopherol Acetate (Vitamin E), Water, White Petrolatum

Skylark

Skylark

Skin Protectant

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

Dermatologist Tested

3.5 OZ. (100 GRAMS)

Skylark Ointment

Skin Protectant

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, buttock, 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 Barbadensis Gel, Chloroxylenol, Cholecalciferol (Vitamin D3), Zea Mays Oil, Fragrance, Lanolin, Mineral Oil, Paraffin, Phenoxyethanol, Retinyl Palmitate (Vitamin A), Sodium Borate, Tocopheryl Acetate (Vitamin E), Water, White Petrolatum

SKYLARK

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71168-8020
Route of Administration	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
SODIUM BORATE (UNII: 91MBZ8H3QO)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
PETROLATUM (UNII: 4T6H12BN9U)	
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)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71168-8020-0	100 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2017	
2	NDC:71168-8020-4	452 g in 1 JAR; Type 0: Not a Combination Product	08/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/01/2017	

Labeler - Skylark CMC (650174824)

Revised: 9/2017 Skylark CMC