

CMC SHIELD SKIN PROTECTANT- zinc oxide cream
SKYLARK CMC PRIVATE LIMITED

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.

CMC-SHIELD

ACTIVE INGREDIENT

Zinc Oxide (3.8%)

PURPOSE

Skin Protectant

USES

- helps treat and prevent diaper rash
- temporarily protects from minor cuts, scrapes
- burns dries the oozing and weeping of poison ivy, poison oak, poison sumac

WARNINGS

For external use only

WHEN USING THIS PRODUCT

- do not get into eyes

STOP USE AND ASK A DOCTOR IF

Condition worsens or symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

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 and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged
- for poison ivy, oak, and sumac
- apply ointment liberally as needed

OTHER INFORMATION

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

INACTIVE INGREDIENTS

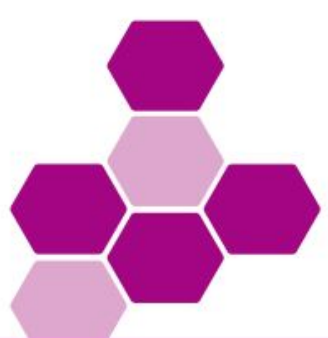
aloe vera leaf, alpha-tocopherol, ceteth-10, cetostearyl alcohol, cetyl alcohol, cholecalciferol, glycerin, lanolin, lavender, methylparaben, mineral oil, paraffin, petrolatum, phenoxyethanol, polyethylene glycol 6000, polysorbate 60, propylparaben sodium, steareth-20, trolamine, vitamin-A, water, FDC Yellow No. 5, DC Red No.21

PACKAGE LABEL

CMC-Shield

SKIN PROTECTANT
ALOE SOFT • VITAMIN ENRICHED

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



Net Wt.
3.5 oz (99.2g)

Reorder No: CMC-1630

Inactive ingredients aloe vera leaf, alpha-tocopherol, ceteth-10, cetostearyl alcohol, cetyl alcohol, cholecalciferol, glycerin, lanolin, lavender, methyl paraben, mineral oil, paraffin, petrolatum, phenoxyethanol, polyethylene glycol 6000, polysorbate 60, propylparaben sodium, steareth-20, trolamine, vitamin A, water, FD&C Yellow No.5, DC Red No. 21

Other information ■ store at room temperature 15°-30°C (59°-86°F) ■ avoid excessive heat

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged
- for poison ivy, oak and sumac ■ apply ointment liberally as often as needed

Warnings For external use only

- When using this product
- do not get into eyes

Uses

- helps treat and prevent diaper rash
- temporarily protects minor ■ cuts ■ scrapes ■ burns ■ dies the oozing and weeping of:
- Poison ivy ■ poison oak ■ poison sumac

Drug Facts

Active ingredient (non-pow)	Purpose
Zinc oxide (3.3% w/w).....Skin Protectant	

CMC-Shield

SKIN PROTECTANT
ALOE SOFT • VITAMIN ENRICHED

CMC SHIELD SKIN PROTECTANT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71168-3066
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
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	

PETROLATUM (UNII: 4T6H12BN9U)
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)
STEARETH-20 (UNII: L0Q8IK9E08)
TROLAMINE (UNII: 9O3K93S3TK)
VITAMIN A (UNII: 81G40H8B0T)
WATER (UNII: 059QF0K00R)
D&C RED NO. 21 (UNII: 08744Z6JNY)
CETYL ALCOHOL (UNII: 936JST6JCN)
LAVENDER OIL (UNII: ZBP1YXW0H8)
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
CETETH-10 (UNII: LF9X1PN3XJ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LANOLIN (UNII: 7EV65EAW6H)
MINERAL OIL (UNII: T5L8T28FGP)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 60 (UNII: CAL22UVI4M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71168-3066-4	99.2 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2017	

Labeler - SKYLARK CMC PRIVATE LIMITED (650174824)

Revised: 9/2017

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