

CMC ZINC OXIDE- zinc oxide ointment
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.

SKYLARK ZINC OXIDE 20% DIAPER RASH CREAM

Active ingredient

Zinc Oxide (20% w/w)

Purpose

Skin Protectant

Purpose

- helps treat and prevent diaper rash
- 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
- do not use over large areas of the body

Stop use and ask a doctor if

- if condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- if you are allergic to any of these ingredients

Keep out of reach of children

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

Directions

- for diaper rash
- 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 any time when exposure to wet diapers may be prolonged
- for poison ivy, oak, sumac
- apply ointment liberally as often as needed

Other information

- store at 56°-86° F (15-30°C)
- avoid excessive heat

Inactive ingredients

cetostearyl alcohol, cetomacrogol 1000, light liquid paraffin, white soft paraffin

PACKAGE LABEL

Reorder No: CMC-1629

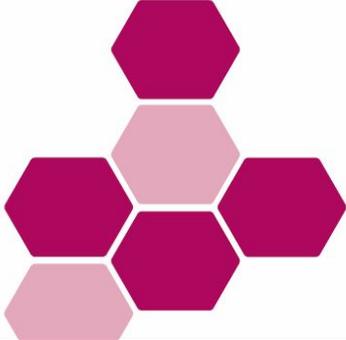
Drug Facts	
Active ingredient	Purpose
Zinc Oxide 20% w/w ... Diaper Rash Cream	
Uses	<ul style="list-style-type: none"> ■ helps treat and prevent diaper rash ■ dries the oozing and weeping of ■ poison ivy ■ poison oak ■ poison sumac
Warnings	<p>For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ do not get into eyes ■ do not use over large areas of the body
Stop use and ask a doctor if	<ul style="list-style-type: none"> ■ the condition worsens ■ symptoms last more than 7 days or clear up and occur again in a few days ■ if you are allergic to any of these ingredients
Keep out of reach of children.	<p>If swallowed, get medical help or contact a Poison Control Center right away</p>
Directions	<ul style="list-style-type: none"> ■ for diaper rash ■ 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 any time when exposure to wet diapers may be prolonged ■ for poison ivy, oak, sumac ■ apply ointment liberally as often as needed
Other information	<ul style="list-style-type: none"> ■ store at 59°-86°F (15°-30°C) ■ avoid excessive heat
Inactive ingredients	<p>cetostearyl alcohol, cetomacrogol 1000, light liquid paraffin, white soft paraffin</p>



Zinc Oxide Ointment

SKIN PROTECTANT

Net Wt.
1 oz (28.3g)



CMC ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71168-3040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71168-3040-3	28 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2017	
2	NDC:71168-3040-4	56 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2017	
3	NDC:71168-3040-5	425 g in 1 JAR; 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

SKYLARK CMC PRIVATE LIMITED