

AFTATE ZINC OXIDE- zinc oxide ointment
Sabel Med LLC

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.

Zinc Oxide Ointment (1 oz and 2 oz)

Active Ingredient (each gram contains)

Zinc oxide 20%

Inactive ingredients

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

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

Purpose

Skin protectant

Directions

- Clean the affected area
- Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to: ■ diaper rash
- helps protect skin from wetness ■ protects and dries oozing and weeping of poison ivy, poison oak and poison sumac
- helps prevent and temporarily protects chafed, chapped, cracked or windburned skin and lips

Warnings

For external use only

- Do not use ■ in the eyes ■ if you are allergic to any of the ingredients
- over large areas of the body ■ longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- condition persists or gets worse
- rash or other allergic reaction develops

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Made in India MH/DRUGS/KD 214

2 mm BG Area can be extend but after formation of the tube will come on back panel



Net wt 1 oz. (28 g)

Zinc Oxide Ointment 20%

NDC 70356-326-01

Quick Diaper Rash Relief

Skin Protectant Helps heal, soothe & prevent diaper rash

Drug Facts Active Ingredient (each gram contains) Zinc oxide 20%		Purpose Skin protectant	Drug Facts (continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Uses <ul style="list-style-type: none"> helps treat and prevent diaper rash protects chafed skin due to: <ul style="list-style-type: none"> diaper rash helps protect skin from wetness protects and dries oozing and weeping of poison ivy, poison oak and poison sumac helps prevent and temporarily protects chafed, chapped, cracked or windburned skin and lips 			Directions <ul style="list-style-type: none"> Clean the affected area Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily May be covered with a sterile bandage
Warnings For external use only Do not use <ul style="list-style-type: none"> in the eyes if you are allergic to any of the ingredients over large areas of the body longer than 1 week unless directed by a doctor 			Other information <ul style="list-style-type: none"> store at 15°-30°C (59°-86°F) avoid excessive heat and humidity Lot No. & Exp. Date : see box or see crimp of tube
Stop use and ask a doctor if <ul style="list-style-type: none"> condition persists or gets worse rash or other allergic reaction develops 			Inactive ingredients cetostearyl alcohol, cetomacrogol 1000, light liquid paraffin, white soft paraffin.
Made in India MH/DRUGS/KD-214			Questions or Comments? Call toll free 888.5Aftate or 888.523.8283 Distributed by: Sabel Med LLC Oldsmar, FL 34677 Aftate™ RetroBrands U.S.A. LLC 2016

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AFTATE ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70356-326
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70356-326-02	56 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	
2	NDC:70356-326-01	28 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2016	

Labeler - Sabel Med LLC (091476000)

Revised: 4/2016

Sabel Med LLC