

ZINC-OXYDE PLUS- menthol, zinc oxide ointment
First Aid Research Corp.

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 Plus

Drug Facts

Active ingredients

Menthol 0.44%

Zinc Oxide 20.6%

Purpose

External analgesic / Anti-itch

Skin protectant / Anorectal astringent

Uses

A moisture barrier that prevents and helps heal skin irritation from: • urine • diarrhea • perspiration • fistula damage • feeding tube site leakage • wound drainage (peri-wound skin) • minor burns • cuts • scrapes • itching

Warnings

For external use only

- not for deep or puncture wounds
- avoid contact with eyes

Stop use and ask a doctor

- if condition worsens or does not improve within 7 days.

Keep out of reach of children. In case of accidental ingestion contact a physician or poison control center immediately.

Directions

- cleanse skin gently with mild skin cleanser
- pat dry or allow to air dry
- apply a thin layer of ointment to reddened or irritated skin 2-4 times daily, or after

each incontinent episode or diaper change to promote comfort and long lasting protection.

Inactive ingredients

butylated hydroxytoluene, calamine, cetyl esters, glycerin, glycerol monostearate, lanolin, PEG-40 hydrogenated castor oil, phenol, sodium bicarbonate, thymol, white petrolatum

Questions?

call **516-783-0274**

IMPROVED FORMULA
ZINC-OXYDE PLUS
With Menthol
 Fragrance Free Ointment

Skin Protectant

Drug Facts		Drug Facts (continued)	
Active ingredients	Purpose	Keep out of reach of children. In case of accidental ingestion contact a physician or poison control center immediately.	
Menthol 0.44%.....	External analgesic / Anti-itch	Directions	
Zinc Oxide 20.6%.....	Skin protectant / Anorectal astringent	<ul style="list-style-type: none"> ■ cleanse skin gently with mild skin cleanser ■ pat dry or allow to air dry ■ apply a thin layer of ointment to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection 	
Uses a moisture barrier that prevents and helps heal skin irritation from: ■ urine ■ diarrhea ■ perspiration ■ fistula damage ■ feeding tube site leakage ■ wound drainage (peri-wound skin) ■ minor burns ■ cuts ■ scrapes ■ itching		Inactive ingredients butylated hydroxytoluene, calamine, cetyl esters, glycerin, glycerol monostearate, lanolin, PEG-40 hydrogenated castor oil, phenol, sodium bicarbonate, thymol, white petrolatum	
Warnings For external use only ■ not for deep or puncture wounds ■ avoid contact with eyes		Questions? call 516-783-0274	
Stop use and ask a doctor ■ if condition worsens or does not improve within 7 days			

Helps Heal Rashes!!

LOT:
EXP:



Made in India
 Distributed by:
 FIRST AID RESEARCH CORP.
 Jupiter, FL 33478

NET WT 2 OZ (57 g)

**No
 Fragrance
 Added**

IMPROVED FORMULA
ZINC-OXYDE PLUS
With Menthol
 Fragrance Free Ointment

IMPROVED FORMULA
ZINC-OXYDE PLUS
With Menthol
 Fragrance Free Ointment



Extreme Rash Treatment!
 Soothes & Heals
 Skin Irritation

ZINC-OXYDE PLUS

menthol, zinc oxide ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75983-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.4 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	206 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PHENOL (UNII: 339NCG44TV)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75983-006-57	1 in 1 CARTON	11/06/2019	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/06/2019	

Labeler - First Aid Research Corp. (089405927)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(75983-006)