NIVAGEN ZINC OXIDE - zinc oxide ointment
Nivagen Pharmaceuticals, Inc.

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 USP

ACTIVE INGREDIENT(S)

Zinc Oxide 20%

USE(S)

Skin Protectant

USES

- Helps treat and prevent diaper rash
- Dries the oozing and weeping of poison: ■ ivy ■ oak ■ sumac

WARNINGS

For External Use Only

When using this product ■ do not get into eyes

Stop use and ask a doctor if

- conditionworsens
- symptoms last more than 7 days or clear up and occur again within a few days

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 as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.
- For poison ivy, oak, and sumac: Apply as needed.

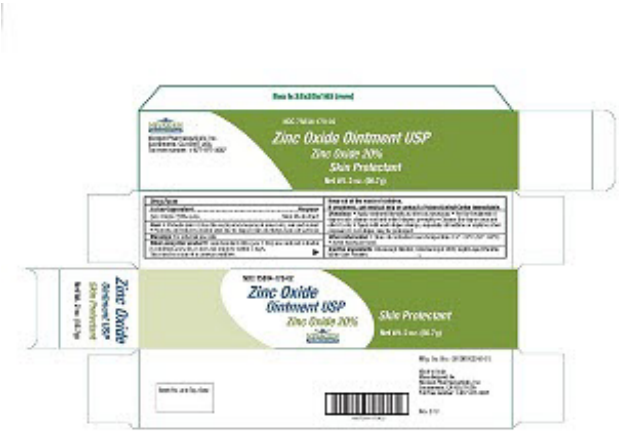
OTHER INFORMATION

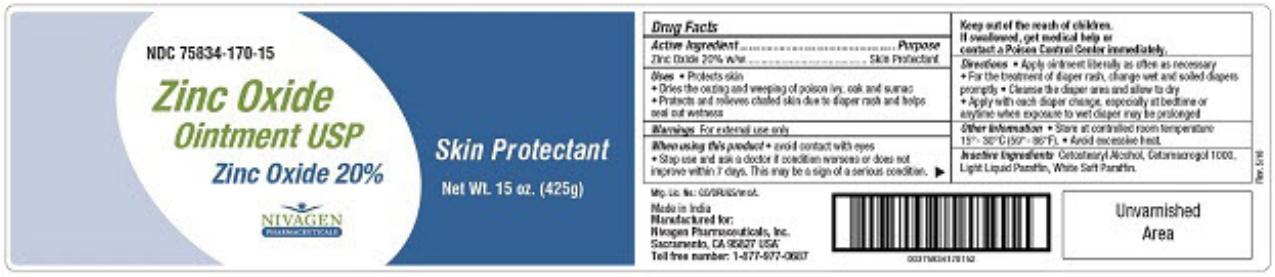
- Store at room temperature
- Avoid excessiveheat

INACTIVE INGREDIENTS

Cetomacrogol 1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin

PRINCIPAL DISPLAY PANEL





NIVAGEN ZINC OXIDE

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75834-170
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75834-170-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	05/10/2018	
2	NDC:75834-170-02	56.7 g in 1 TUBE; Type 0: Not a Combination Product	05/10/2018	
3	NDC:75834-170-15	425 g in 1 JAR; Type 0: Not a Combination Product	05/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	05/10/2018	

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 2/2022 Nivagen Pharmaceuticals, Inc.