

**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.*

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**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

- condition worsens
- 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 excessive heat

## INACTIVE INGREDIENTS

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

## PRINCIPAL DISPLAY PANEL




NDC 75834-170-15

# Zinc Oxide Ointment USP

Zinc Oxide 20%

**Skin Protectant**

Net Wt. 15 oz. (425g)



**Drug Facts**

**Active Ingredient** Zinc Oxide 20% w/w **Purpose** Skin Protectant

**Uses** • Protects skin  
• Dries the oozing and weeping of poison ivy, oak and sumac  
• Protects and relieves chafed skin due to diaper rash and helps seal out wetness

**Warnings** For external use only  
• When using this product • avoid contact with eyes  
• Stop use and ask a doctor if condition worsens or does not improve within 7 days. This may be a sign of a serious condition.

**Other information** • Store at controlled room temperature 15°-30°C (59°-86°F). • Avoid excessive heat.


**Inactive Ingredients** Cetostearyl Alcohol, Cetanolicol 1000, Light Liquid Paraffin, White Soft Paraffin.

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

Directions • Apply ointment liberally as often as necessary  
• For the treatment of diaper rash, change wet and soiled diapers promptly • Cleanse the diaper area and allow to dry  
• Apply with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged

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

Net Wt. 15 oz.



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Unwarmed Area

## NIVAGEN ZINC OXIDE

zinc oxide ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75834-170
<b>Route of Administration</b>	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	

