DYNAREX ZINC OXIDE- zinc oxide ointment ointment
Dynarex Corporation

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.

1190 Zinc Oxide Ointment NDC 67777-119-00
1191 Zinc Oxide Ointment NDC 67777-119-10
1192 Zinc Oxide Ointment NDC 67777-119-20

Active Ingredient

Zinc Oxide 25%

Purpose

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.

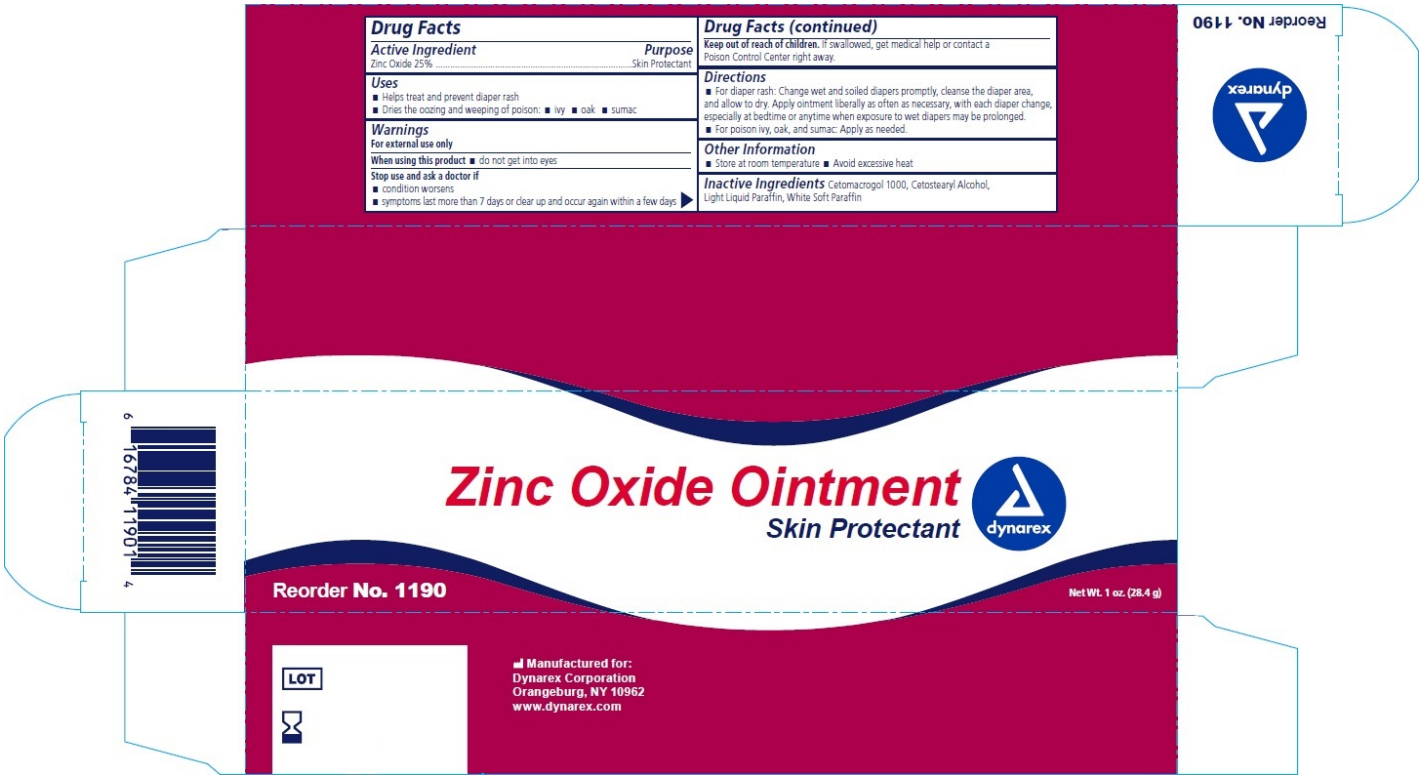
Other Information

- Store at room temperature
- Avoid excessive heat

Inactive Ingredients

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

Labeling


Drug Facts
Active Ingredient
Zinc Oxide 25%
Purpose
Skin Protectant
Uses
■ Helps treat and prevent diaper rash
■ Dries the oozing and weeping of poison: ■ ivy ■ oak ■ sumac
Warnings
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Stop use and ask a doctor if
■ condition worsens
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Drug Facts (continued)
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions
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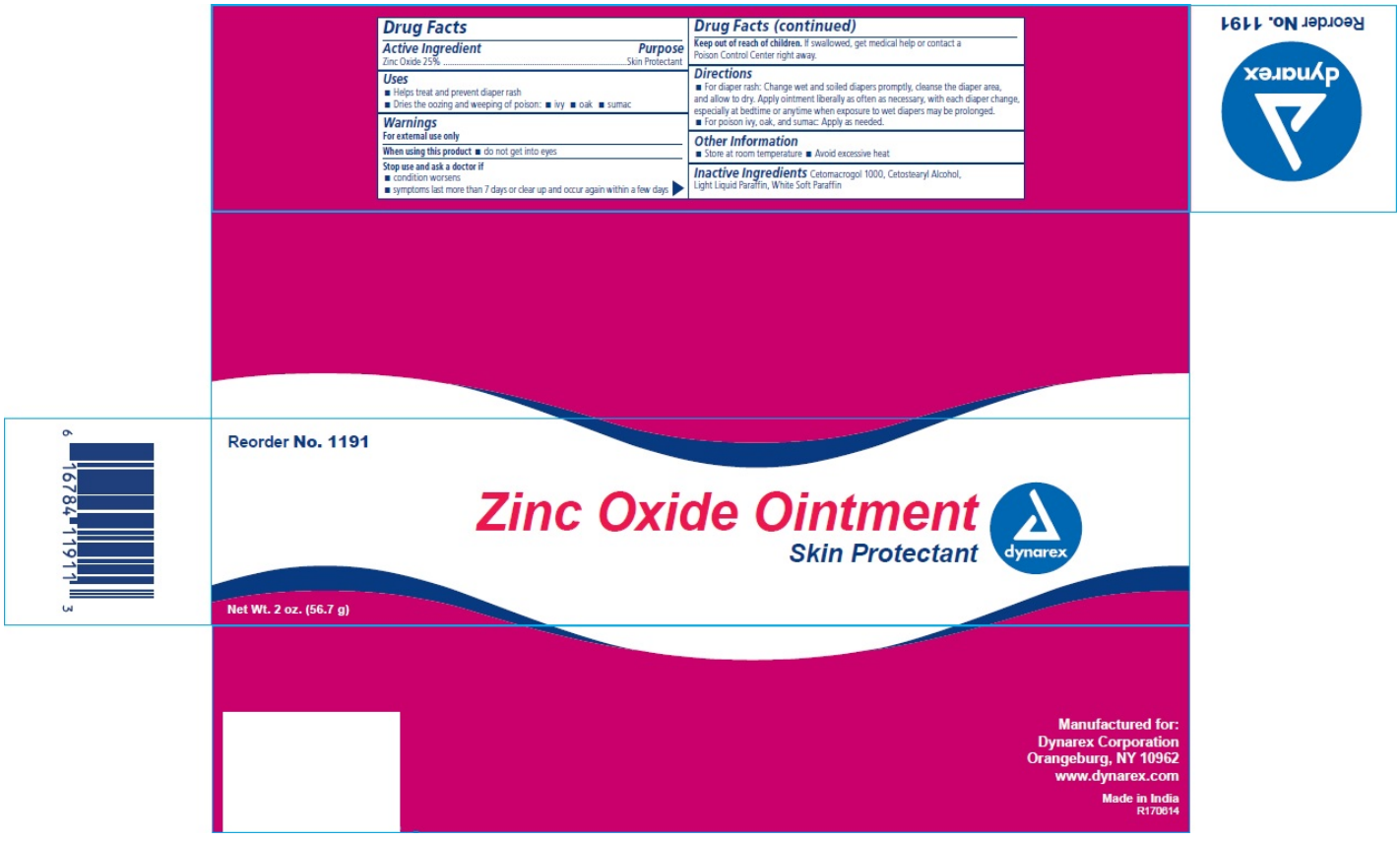
Inactive Ingredients Cetomacrogol 1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin
Reorder No. 1190
dynarex
Zinc Oxide Ointment
Skin Protectant
Reorder No. 1190
Net Wt. 1 oz. (28.4 g)
LOT
Manufactured for:
Dynarex Corporation
Orangeburg, NY 10962
www.dynarex.com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Other Information
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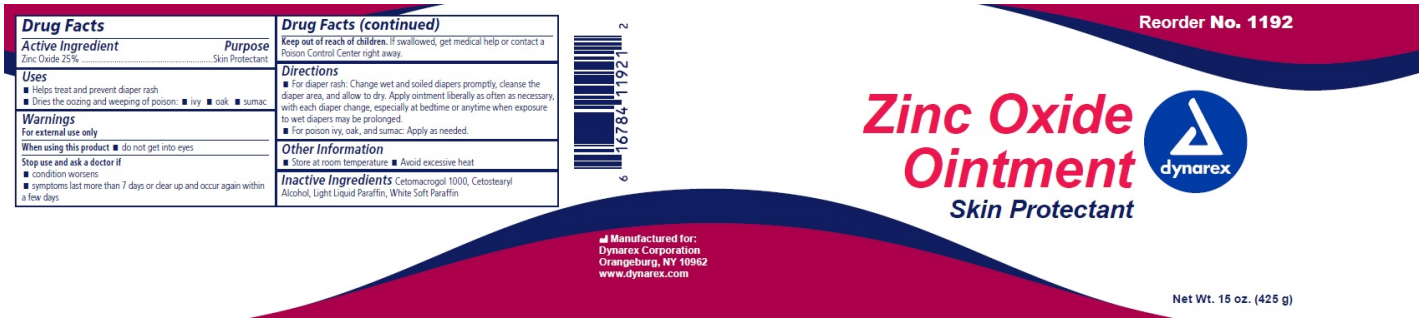
Inactive Ingredients Cetomacrogol 1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin
Reorder No. 1191
dynarex
Reorder No. 1191
Zinc Oxide Ointment
Skin Protectant
Net Wt. 2 oz. (56.7 g)
Manufactured for:
Dynarex Corporation
Orangeburg, NY 10962
www.dynarex.com
Made in India
R170614



DYNAREX ZINC OXIDE

zinc oxide ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	250 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:67777-119-00	28.4 g in 1 TUBE; Type 0: Not a Combination Product	03/27/2018	
2	NDC:67777-119-10	56.7 g in 1 TUBE; Type 0: Not a Combination Product	03/27/2018	
3	NDC:67777-119-20	425 g in 1 JAR; Type 0: Not a Combination Product	03/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/27/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 2/2019 Dynarex Corporation