ZINC OXIDE- zinc oxide 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.

Zinc Oxide Ointment

Section Text

Active Ingredient	Purpose
Zinc Oxide (200mg in each gram)	Skin Protectant

Purpose:

- Helps treat and prevent diaper rash.

- Dries the oozing and weeping of;
- poison ivy
- poison oak
- poison sumac

Warnings:

For External Use Only

When using this product:
- Do not get in eyes.

Stop use and ask a doctor if:
- conditions worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician.
- over large areas of the body
- if you are allergic to any of these ingredients

Do not use on:
- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

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 with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

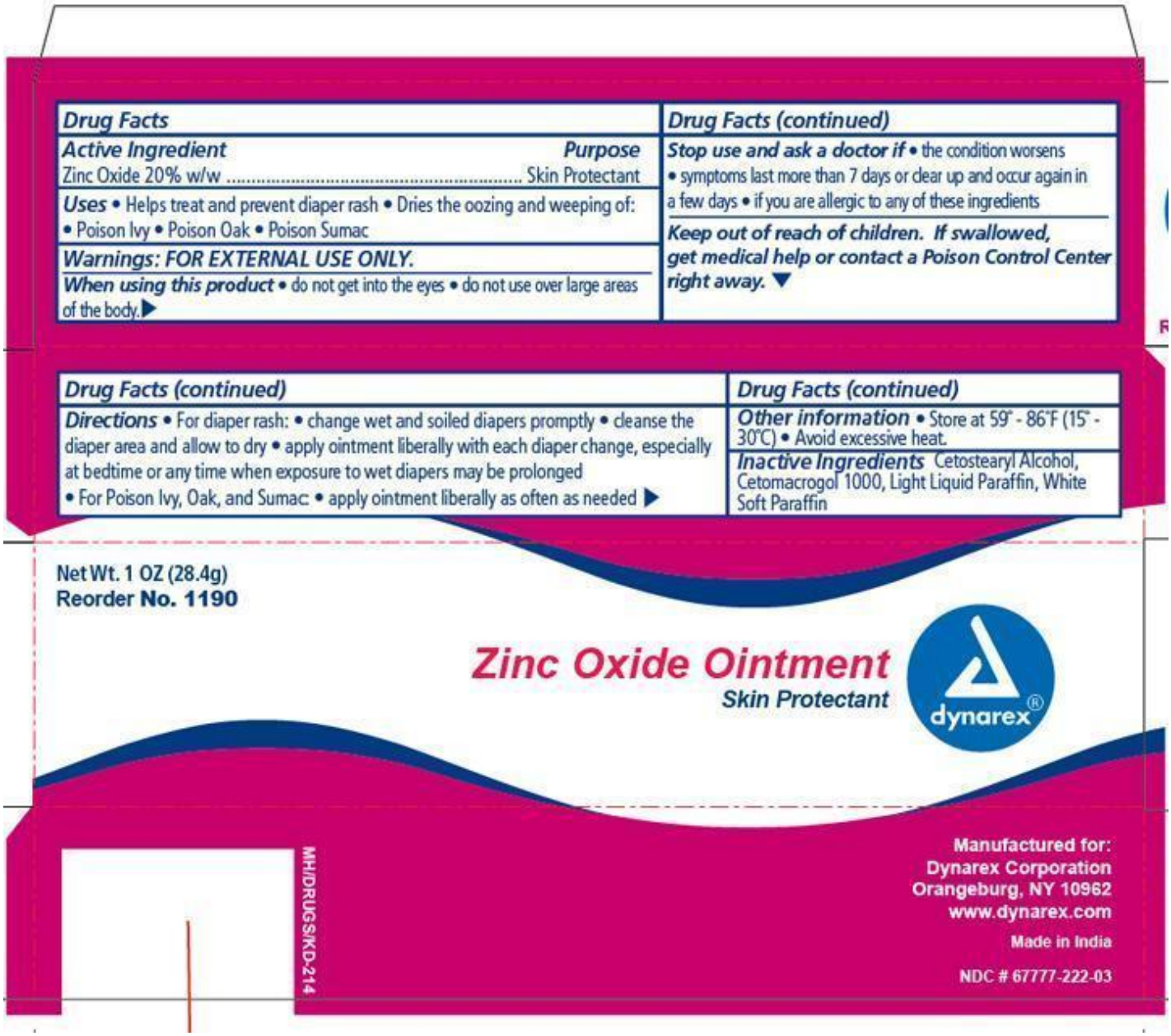
For poison ivy, poison oak, poison sumac:
- apply liberally as often as needed

Inactive Ingredients

Cetostearyl alcohol, Cetomacrogal 1000, Light Liquid Paraffin, White Soft Paraffin

Principal Display

zinc.jpg



ZINC OXIDE zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-222
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)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-222-03	28.34 g in 1 TUBE; Type 0: Not a Combination Product	03/17/2010	
2	NDC:67777-222-01	56.68 g in 1 TUBE; Type 0: Not a Combination Product	03/17/2010	
3	NDC:67777-222-02	425.1 g in 1 JAR; Type 0: Not a Combination Product	03/17/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/16/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Pvt. Ltd.		864201135	manufacture(67777-222)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Pvt. Ltd.		650970176	manufacture(67777-222)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(67777-222)