

RUGBY ZINC OXIDE- zinc oxide ointment

Rugby Laboratories

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.

Drug Facts

Active ingredient

Zinc oxide 20%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.
- dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Warnings

For external use only

When using this product, avoid contact with the eyes

Stop use and ask a doctor if condition worsens or does not improve within 7 days

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- apply liberally as often as necessary

For diaper rash:

- change wet or soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally, as often as necessary, with each diaper change and especially at bedtime or anytime when exposure to wet diapers may be prolonged

Inactive ingredients

mineral oil, petrolatum

Questions or comments?

Call **1-800-645-2158** 9 am - 5 pm EST, Monday – Friday

Store at room temperature 15° - 30°C (59° - 86°F).

R0507

Principal Display Panel – Jar Label

Rugby® NDC 0536-5700-98
SKIN PROTECTANT

Zinc Oxide
Ointment USP

- provides soothing relief from poison ivy, oak and sumac
- Treats and prevents diaper rash

Net Wt 1 lb (454 g)

Mfd for: Rugby Laboratories, Inc.
 Duluth, Georgia 30097

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Satisfaction Guaranteed
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RUGBY ZINC OXIDE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-5700
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
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-5700-98	454 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/23/2004	

Labeler - Rugby Laboratories (191427277)

Registrant - Faria Limited dba Sheffield Pharmaceuticals (151177797)

Establishment			
Name	Address	ID/FEI	Business Operations
Faria LLC dba Sheffield Pharmaceuticals		151177797	MANUFACTURE(0536-5700)

Revised: 1/2013

Rugby Laboratories