# 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

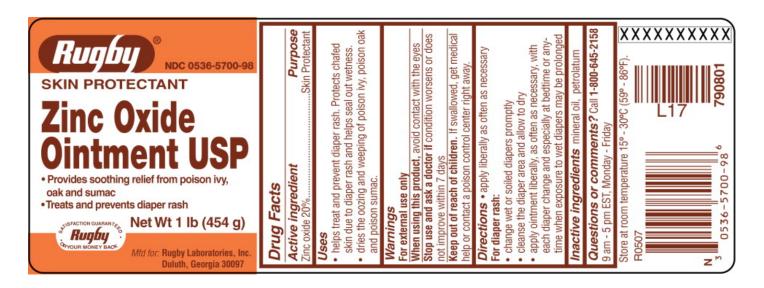
Zinc Oxide Ointment USP

- 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



#### RUGBY ZINC OXIDE

zinc oxide ointment

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0536-5700
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL O IL		
PETROLATUM		

# 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 Monogra	ph Citation	Marketing Start D	ate Marketing End Date
OTC monograph final	part347	C	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