

## **BACITRACIN ZINC- bacitracin zinc 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.*

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## **Rugby Bacitracin Zinc Ointment**

### **Active Ingredient**

Bacitracin Zinc 500 Units per gram

### **Purpose**

First Aid Antibiotic

### **Uses**

First Aid to help prevent infection in

- minor cuts
- scrapes
- burns

### **Warnings**

**For External Use Only.**

### **Do Not Use**

- in eyes
- over large areas of the body
- if you are allergic to any of the ingredients
- longer than 1 week unless directed by a doctor

### **Ask Doctor before Use**

In care of deep puncture wounds, animal bites, or serious burns.

### **Stop Use and Ask Doctor if**

- The condition persists or gets worse
- A rash or allergic reaction develops

### **Directions**

- Clean the affected area

- Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

### **Inactive Ingredients**

Aloe barbadensis leaf juice, mineral oil, petrolatum

### **Questions**

Call 1-800-645-2158

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center immediately.

### **Other Information**

Store Between 15° to 25°C (59° to 77°F)

Lot No. and Expiration Date: See box and tube crimp

Distributed By:

RUGBY LABORATORIES

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

[www.rugbylaboratories.com](http://www.rugbylaboratories.com)

1-800-645-2158

Made in China

### **Packaging**

# OUTSIDE BOX



# INNER TUBE



bacitracin zinc ointment

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0536-1263 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>   | <b>Basis of Strength</b> | <b>Strength</b>    |
|--|--------------------------|--------------------|
| <b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I) | BACITRACIN               | 500 [USP'U] in 1 g |

### Inactive Ingredients

| <b>Ingredient Name</b>                   | <b>Strength</b> |
|--|-----------------|
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)    |                 |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)     |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X) |                 |

### Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:0536-1263-28 | 1 in 1 BOX  | 04/15/2020                  |                           |
| 1        |                  | 28 g in 1 TUBE; Type 0: Not a Combination Product |                             |                           |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part333B  | 04/15/2020                  |                           |

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 7/2023

Rugby Laboratories