BACITRACIN ZINC- bacitracin zinc ointment Blossom Pharmaceuticals

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.

Bacitracin Zinc Ointment

Active ingredient Purpose
Bacitracin Zinc 500 Units Antibiotic

Warnings:

For external use only

Dosage & Administration

clean the affected areas

apply a small amount of product (an amount equal to the surface area of the tip of the finger) on the area 1 to 3 times daily

may be covered with a sterile bandage

Indications & Usage

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

KEEP OUT OF REACH OF CHILDREN

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If swallowed, get medical help or contact a Poison Control Center right away

Purpose:

First aid to help prevent infection in:

- Minor cuts
- scrapes
- burns

Ask a doctor before use:

- in case of deep or puncture wounds
- animal bites
- serious burns

Other information

• store at controlled room temperature 15°-30° C (59°-86° F)

Stop Use and ask a doctor if

• the condition persists or gets worse, or if a rash or other allergic reaction develops.

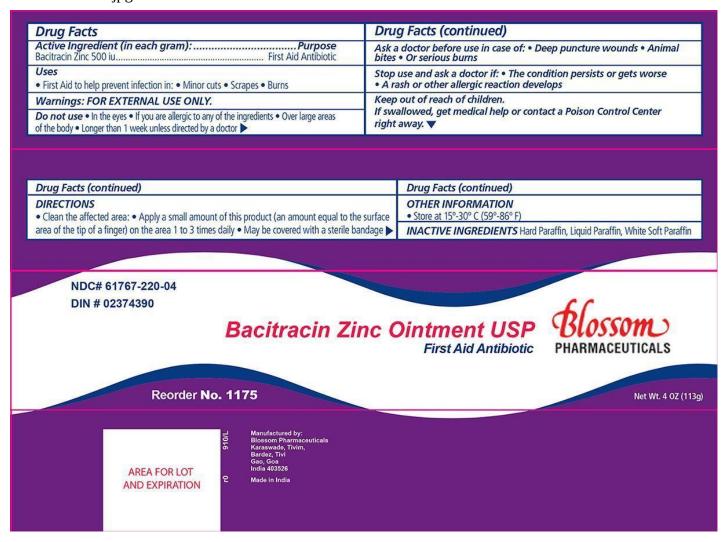
Inactive ingredients

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

Principal Display Panel

Blossom Pharmaceuticals Bacitracin Zinc Ointment:

bacitracin zinc.jpg



BACITRACIN ZINC

bacitracin zinc ointment

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61767-220 |
| Route of Administration | TOPICAL | | |
| | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------------|
| BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I) | BACITRACIN | 500 [USP'U] in 1 g |

| Inactive Ingredients | | |
|--------------------------------------|----------|--|
| Ingredient Name | Strength | |
| PETROLATUM (UNII: 4T6H12BN9U) | | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | |
| MINERAL OIL (UNII: T5L8T28FGP) | | |

| Packaging | | | | |
|-----------|------------------|---------------------|-----------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61767-220-02 | 28.35 g in 1 TUBE | | |
| 2 | NDC:61767-220-03 | 14.17 g in 1 TUBE | | |
| 3 | NDC:61767-220-04 | 113.4 g in 1 TUBE | | |
| 4 | NDC:61767-220-07 | 425.3 g in 1 JAR | | |
| 5 | NDC:61767-220-05 | 0.5 g in 1 PACKET | | |
| 6 | NDC:61767-220-01 | 0.9 g in 1 PACKET | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part333B | 05/14/2014 | |
| | | | |

Labeler - Blossom Pharmaceuticals (677381470)

| Establishment | | | | |
|-------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Blossom Pharmaceuticals | | 677381470 | manufacture(61767-220) | |

Revised: 5/2014 Blossom Pharmaceuticals