**FIRST AID ANTIBIOTIC BACITRAYCIN PLUS MAXIMUM STRENGTH- bacitracin and pramoxine hcl ointment**
**Anicare Pharmaceuticals Pvt. Ltd**

*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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**First Aid Antibiotic Bacitraycin Plus Maximum Strength Ointment**

**Active ingredient (each gram contains)**

Bacitracin 500 units

Pramoxine HCl 10 mg

**Purpose**

First Aid Antibiotic

Pain Reliever

**Uses**

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

**Warnings**

**For external use only.**

**Do not use**

- in the 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 a doctor before use** in case of deep or puncture wounds, animal bites, or serious burns.

**Stop use and ask a doctor if**

- the condition persists or gets worse
- a rash or other allergic reaction develops

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**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

**Other information**

- store at 15° to 25° C (59° to 77° F)
- Lot No. & Exp. Date: see box or see crimp of tube

**Inactive ingredients**

aloe vera leaf, methylparaben, mineral oil, petrolatum, propylparaben, stearyl alcohol

**Distributed by:**

**First Aid Research Corp.**

Jupiter, FL 33478

Made in India


# FIRST AID ANTIBIOTIC BACITRAYCIN PLUS MAXIMUM STRENGTH

bacitracin and pramoxine hcl ointment

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:47046-163 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BACITRACIN** (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I) | BACITRACIN | 500 [USP'U] in 1 g |
| **PRAMOXINE HYDROCHLORIDE** (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 10 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |

| | |
|---|---|
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:47046-163-02 | 1 in 1 CARTON | 02/20/2018 | |
| **1** | NDC:47046-163-01 | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part333B | 02/20/2018 | |

## Labeler - Anicare Pharmaceuticals Pvt. Ltd (916837425)

## Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Anicare Pharmaceuticals Pvt. Ltd | | 916837425 | manufacture(47046-163) |

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd