



MYCITRACIN[®]-Plus Pain Reliever

Triple Antibiotic First Aid Ointment

1. NAME OF THE MEDICINAL PRODUCT

MYCITRACIN[®] PLUS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Gram Contains:

Bacitracin	500 Units
Neomycin Sulphate	Equivalent to 3.5 mg Neomycin
Polymyxin B Sulphate	5000 Units
Lidocaine	40 mg

Also contains butyl paraben, cholesterol, methyl paraben, microcrystalline wax, mineral oil and white petrolatum.²

3. PHARMACEUTICAL FORM

Ointment

Benefits over other dosage forms:

Topical formulation of antimicrobials exhibit better delivery to skin and soft tissue cells than orally dosed formulations and are also effective in preventing infection in open wounds and promoting faster healing.

Topical application of antimicrobials to normal, psoriatic or atopic areas have not been shown to diffuse into the blood stream in appreciable quantities.

Oral and parenteral formulations of the individual components of Triple Antibiotic Ointment may cause serious systemic toxicities, which preclude their use as intravenous antibiotics.¹

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

First aid to help prevent infections and temporarily relieve pain in minor burns, cuts, nicks, scrapes, scratches and abrasions.¹

Purpose

Triple Antibiotic Ointment is active against the most common disease-causing pathogens found in wounds and on the skin and may be an attractive alternative to oral therapy in select circumstances.¹

Mycitracin Plus Pain Reliever combines three antibiotics with a pain reliever in a soothing, non-irritating petrolatum base that aids healing, helps prevent infection and temporarily relieves pain.

Preventive treatment:

Minor Traumatic Wounds (cuts, scrapes and burns):

Use of antibiotic ointment in minor traumatic wounds offers three important benefits: prophylaxis, bacterial eradication and faster wound healing time, because it is known that a moist environment promotes speedy wound healing.

It also promotes wound healing by decreasing transepidermal water loss through occlusion.¹

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Adults & Children (12 Years & Older):²

Use exactly as directed on the label, or as prescribed by your doctor. Do not use in larger or smaller amounts or for longer than recommended.

Before you apply this medication, wash the skin area with soap and water and then dry it thoroughly.

Apply small amount of Mycitracin Plus Pain Reliever (an amount equal to the surface area of the tip of a finger) on the affected area 1 to 3 times daily.

Cover the affected area with the sterile bandage.

Not recommended for children under 12 years of age.

4.3. CONTRAINDICATIONS

Information not available.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE²

For external use only.

Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a physician.

Not recommended for the people who are allergic to any of the ingredients.

Stop use and consult a physician if your symptoms do not improve after 7 days of treatment, or if they get worse.

Do not use longer than 1 week unless directed by a physician.

Keep this and all medication, out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Information not available.

4.6. FERTILITY, PREGNANCY AND LACTATION

FDA pregnancy category C. It is not known whether bacitracin, neomycin, and polymyxin B is harmful to an unborn baby. Before using this medication, tell your doctor if you are pregnant or plan to become pregnant during treatment.

Not known if this medicine passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.⁴

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Information not available.

4.8. UNDESIRABLE EFFECTS

Most common side effects include:

Itching, skin rash, redness, swelling, or other sign of irritation.⁵

4.9. OVERDOSE

Information not available.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Neomycin, an aminoglycoside, inhibit protein synthesis by binding to the bacterial 30S ribosomal subunit and interfering with mRNA translation. It is active against many gram negative organisms and several species of staphylococci.

Bacitracin inhibits the dephosphorylation of C55-isoprenyl pyrophosphate, a biophosphate lipid transport molecule essential for the synthesis of the peptidoglycan bacterial cell wall. It is active against staphylococcal species.

Polymyxin, an antimicrobial peptide, exhibits its antimicrobial effects by increasing bacterial cell wall permeability. It is highly active against *P. aeruginosa*, the third most common organism isolated from wounds.¹

Lidocaine, it binds to sodium channels. The amide on the lidocaine allows it to act like an amino acid and interact with the active site in the sodium channel domain. It works by stopping the sodium ions from passing through the voltage-gated channels. So the signals of the pain are stopped even before the signals are formed.³

5.2. PHARMACOKINETIC PROPERTIES

Information not available.

5.3. PRECLINICAL SAFETY DATA

Information not available.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS

Microcrystalline Wax NF

White Petrolatum USP

Mineral Oil USP

Cholesterol NF

Methyl Paraben NF

Butyl Paraben NF

Lidocaine USP

Neomycin Sulfate USP Micronized

Bacitracin USP Powder Micronized
Polymyxin B Sulfate USP Micronized

6.2. INCOMPATIBILITIES

Information not available.

6.3. SHELF LIFE

24 months

6.4. SPECIAL PRECAUTIONS FOR STORAGE

Store at 15°-25° C (59°-77°F).
Tamper evident sealed packets
Do not use any opened or torn packets.²

6.5. NATURE AND CONTENTS OF CONTAINER

Information not available.

Mycitracin LPD/PK-01

Manufactured by:

Pfizer Pakistan Limited
B-2, S.I.T.E., Karachi-Pakistan.

7. REFERENCES

1. *Topical Triple Antibiotic ointment as a novel therapeutic choice in wound management and infection prevention: a practical perspective.* Robert A Bonomo, Peter S Van Zile, et.al. 5, 2007. *Anti Infect. Ther.*, Vol. 5, pp. 773-782.
2. FIRST AID TRIPLE ANTIBIOTIC WITH PAIN RELIEVER- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine ointment. *NIH- U.S National Library of Medicine.* [Online] Revised September 15, 2010. [Cited: August 3, 2018.] <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fc0dc0be-1d9b-4ff0-ab48-b0fdd7b1cfce>.
3. **Foist, Laura.** Lidocaine: Structure & Mechanism of Action-Lesson 3. *Study.Com.* [Online] [Cited: August 3, 2018.] <https://study.com/academy/lesson/lidocaine-structure-mechanism-of-action.html>.
4. bacitracin, neomycin, and polymyxin B (topical) (Medi-Quik, Neosporin, Triple Antibiotic). *EMedicine Health.* [Online] [Cited: August 3, 2018.] https://www.emedicinehealth.com/drug-bacitracin_neomycin_and_polymyxin_b_topical/article_em.htm#important.
5. Triple Antibiotic (topical). *Drugs.com.* [Online] Last Reviewed June 2018. [Cited: August 3, 2018.] <https://www.drugs.com/mtm/triple-antibiotic-topical.html>.