

For the Use of a Registered Medical Practitioner Only

1. GENERIC NAME AND BRAND NAME

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment USP
NEBASULF® OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram Contains:

Polymyxin B Sulfate I.P.

e.q. to Polymyxin B..... 5000 Units

Bacitracin Zinc I.P. 400 Units

Neomycin Sulphate I.P. eq. to Neomycin.....3400 Units

Ointment Base q.s.

3. DOSAGE FORM AND STRENGTH

Kindly refer to section 1 & 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Indicated in conditions where superficial bacterial skin infection is present or likely to occur, these include:

- Prophylaxis in graft donor sites, the suturing of lacerations, accidental cuts, scratches and abrasions.
- Treatment of infected ulcers, accidental cuts, scratches and abrasions and superficial skin infections following surgical procedures and minor burns, impetigo and secondarily infected skin conditions.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Topical Apply a small amount on the affected area 1 to 3 times daily.

General Advice:

For external use only. Not for use in the eyes.

Do not use over large areas of the body.

Clean the affected area before use.

Affected area may be covered with a bandage after application.

4.3 CONTRAINDICATIONS

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment is contraindicated in individuals who have shown hypersensitivity to any of its components.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical antibiotics is not known.

The manifestations of sensitization to topical antibiotics are usually itching, reddening. A sensitization reaction may manifest simply, as a failure to heal. During long-term use of topical antibiotic products, periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. Symptoms usually subside quickly on withdrawing the medication.

4.5 DRUGS INTERACTIONS

Not well documented

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy:

Teratogenic effects -Pregnancy Category C.

Animal reproduction studies have not been conducted with polymyxin B sulfate or bacitracin. It is also not known whether Bacitracin Zinc and Polymyxin B Sulfate Ointment can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacitracin Zinc and Polymyxin B Sulfate Ointment should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Bacitracin Zinc and Polymyxin B Sulfate Ointment is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None Known

4.8 UNDESIRABLE EFFECTS

Allergic hypersensitivity (itching and swelling)

Miscellaneous:

Hypersensitivity reactions, including anaphylaxis (rare); local irritation on instillation.

Precautions:**Monitor**

During long term use, monitor the sign of sensitization reaction.

Pregnancy:

Category C.

Lactation:

Undetermined.

Hypersensitivity:

Cutaneous sensitization may occur, particularly manifested as itching, reddening, and edema, or as a failure to heal.

Superinfection:

Prolonged use may result in bacterial or fungal overgrowth of nonsusceptible microorganisms.

Cross-sensitivity:

Allergic cross-sensitivity to kanamycin, paromomycin, streptomycin, and, possibly, gentamicin may occur.

Resistance:

Bacterial resistance to these antibiotics may develop.

Secondary infection:

Secondary bacterial ocular infection following suppression of host responses may occur

4.9 OVERDOSAGE

Following accidental ingestion, minimal absorption is expected. No specific symptoms or signs have been associated with excessive use. However, consideration should be given to significant systemic absorption.

Treatment: Blood levels of Neomycin Sulphate, Polymyxin B Sulfate and Bacitracin Zinc should also be determined, and hemodialysis may reduce the serum level of Neomycin Sulphate.

5. PHARMACOLOGICAL PROPERTIES**5.1 MECHANISM OF ACTION****Bacitracin Zinc:**

Bacitracin interferes with the dephosphorylation of the 55-carbon, biphosphate lipid transport molecule C55-isoprenyl pyrophosphate (undecaprenyl pyrophosphate), which carries the building blocks of the peptidoglycan bacterial cell wall outside the inner membrane for construction. Bacitracin binds divalent transition metal ions (Mn (II), Co(II), Ni(II), Cu(II), and Zn(II)) which binds and oxidatively cleave DNA.

Polymyxin B Sulfate:

Polymyxin B sulfate has a bactericidal action against almost all gram-negative bacilli except the Proteus group. Polymyxin B sulfate interacts with the lipopolysaccharide of

the cytoplasmic outer membrane of Gram-negative bacteria, altering membrane permeability and causing cell death. It does not need to enter the cell.

Neomycin Sulphate:

Aminoglycosides like neomycin "irreversibly" bind to specific 30S-subunit proteins and 16S rRNA. Specifically neomycin binds to four nucleotides of 16S rRNA and a single amino acid of protein S12. This interferes with decoding site in the vicinity of nucleotide 1400 in 16S rRNA of 30S subunit. This region interacts with the wobble base in the anticodon of tRNA. This leads to interference with the initiation complex, misreading of mRNA so incorrect amino acids are inserted into the polypeptide leading to nonfunctional or toxic peptides and the breakup of polysomes into nonfunctional monosomes.

5.2 PHARMACODYNAMIC PROPERTIES

Bacitracin Zinc:

Bacitracin is a mixture of related cyclic polypeptides produced by organisms of the licheniformis group of *Bacillus subtilis* var Tracy. As a polypeptide, toxic, and difficult to use chemically, bacitracin doesn't work well orally, however is very effective topically. Bacitracin exerts pronounced antibacterial action in vitro against a variety of gram-positive and a few gram-negative organisms. However, among systemic diseases, only staphylococcal infections qualify for consideration of bacitracin therapy.

Polymyxin B Sulfate:

Polymyxin B sulfate is a mixture of polymyxins B1 and B2, obtained from *Bacillus polymyxa* strains.

They are basic polypeptides of about eight amino acids and have cationic detergent action on cell membranes. Polymyxin B is used for infections with gram-negative organisms, but may be neurotoxic and nephrotoxic. All gram-positive bacteria, fungi, and the gram-negative cocci, *N. gonorrhoea* and *N. meningitidis*, are resistant.

Neomycin Sulphate:

Neomycin is an aminoglycoside antibiotic. Aminoglycosides work by binding to the bacterial 30S ribosomal subunit, causing misreading of t-RNA, leaving the bacterium unable to synthesize proteins vital to its growth. Aminoglycosides are useful primarily in infections involving aerobic, Gram-negative bacteria, such as *Pseudomonas*, *Acinetobacter*, and *Enterobacter*.

In addition, some mycobacteria, including the bacteria that cause tuberculosis, are susceptible to aminoglycosides. Infections caused by Gram-positive bacteria can also be treated with aminoglycosides, but other types of antibiotics are more potent and less damaging to the host. In the past the aminoglycosides have been used in conjunction with penicillin-related antibiotics in streptococcal infections for their synergistic effects, particularly in endocarditis. Aminoglycosides are mostly ineffective against anaerobic bacteria, fungi and viruses.

5.3 PHARMACOKINETIC PROPERTIES

Neomycin Sulphate: Absorption through skin is limited. Topical application of Neomycin in petrolatum does not result in detectable drug concentrations in either serum or urine.

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with polymyxin B sulfate or bacitracin or Neomycin. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on male or female fertility, litter size, or survival were observed in rabbits given bacitracin zinc 100 gm/ton of diet.

7. DESCRIPTION

NEBASULF OINTMENT is supplied for external application, as an ointment dosage form. Each pack of NEBASULF OINTMENT contains Neomycin and Polymyxin B Sulfates and Bacitracin Zinc.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not Applicable

8.2 SHELF-LIFE

Refer pack

8.3 PACKAGING INFORMATION

Refer pack

8.4 STORAGE CONDITION AND HANDING INSTRUCTIONS

Refer pack

9. PATIENT COUNSELLING INFORMATION

Advise patients to discontinue the product if they observe signs and symptoms of cutaneous sensitization including itching, reddening, and edema.

10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

MARKETED BY:

Abbott Healthcare Pvt. Ltd.

Angel Space, Bldg. D-4, Gala No. 1 to 6 &
11 to 16 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER

Refer Pack for Permission/License details

12. DATE OF REVISION

Version 2.0, Dated 18th October 2023

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com