Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

BACTOSPORIN (Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment USP)

2. Qualitative and quantitative composition

BACTOSPORIN ANTIBIOTIC OINTMENT (*for ophthalmic use)*
Each gram contains:
Neomycin Sulfate USP 3400 units
Polymyxin B Sulfates USP 5000 units
Bacitracin Zinc USP 400 units

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Ointment

An off-white ointment.

4. Clinical particulars

4.1 Therapeutic indications

BACTOSPORIN ointment is indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria. Such infections encompass conjunctivitis, keratitis and keratoconjunctivitis, blepharitis and blepharoconjunctivitis.

4.2 Posology and method of administration

Posology

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

Method of administration

Topical

4.3 Contraindications

BACTOSPORIN ointment is contraindicated in individuals who have shown hypersensitivity to any of its components.

4.4 Special warnings and precautions for use

Warnings

NOT FOR INJECTION INTO THE EYE. Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment, USP should never be directly introduced into the anterior chamber of the eye. Ophthalmic ointments may retard corneal wound healing.

Topical antibiotics, particularly neomycin sulfate, 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, and oedema of the conjunctiva and eyelid. 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. Application of products containing these ingredients should be avoided for the patient thereafter.

Precaution

General: As with other antibiotic preparations, prolonged use of Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP may result in the overgrowth of nonsusceptible organisms including fungi. If superinfection occurs, appropriate measures should be initiated.

Bacterial resistance to Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP may also develop. If purulent discharge, inflammation, or pain becomes aggravated, the patient should discontinue the use of the medication and consult a physician.

There have been reports of bacterial keratitis associated with the use of topical ophthalmic products in multiple-dose containers, which have been inadvertently contaminated by patients,

most of whom had a concurrent corneal disease or a disruption of the ocular epithelial surface. Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin and possibly gentamicin.

Information for Patients: Patients should be instructed to avoid allowing the tip of the dispensing container to contact with the eye, eyelid, fingers, or any other surface. The use of this product by more than one person may spread infection.
Patients should also be instructed that ocular products if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated products

If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician, Do not use this product if you are allergic to any of the listed ingredients.

4.5 Interaction with other medicinal products and other forms of interaction

Aminoglycosides, and other (concurrent topical and systemic use with neomycin or related drugs is not recommended since hypersensitivity reactions may occur more frequently during concurrent use.

4.6 Fertility, pregnancy, and lactation

Pregnancy: Teratogenic Effects: Pregnancy Category C Animal reproduction studies have not been conducted with neomycin sulphate, polymyxin B sulphate, or bacitracin. It is also not known whether Neomycin and Polymyxin B Sulphates and Bacitracin Zinc Ophthalmic Ointment, USP can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Neomycin and Polymyxin B Sulphates and Bacitracin Zinc Ophthalmic Ointment, USP should be given to pregnant women 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 Neomycin and Polymyxin B Sulphates and Bacitracin Zinc Ophthalmic Ointment, USP is administered to a nursing woman.
Paediatric Use: Safety and effectiveness in paediatric patients have not been established.
Geriatric Use: No overall differences in safety or effectiveness have been observed between
elderly and younger patients.

4.7 Effects on ability to drive and use machines.

Bacitracin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions have occurred with the anti-infective components of Neomycin and Polymyxin B Sulfate and Bacitracin Zinc Ophthalmic Ointment, USP. The exact incidence is not known. Reactions occurring most often are allergic sensitization reactions including itching, swelling, and conjunctival erythema. More serious hypersensitivity reactions, including anaphylaxis, have been reported rarely.

Local irritation on instillation has also been reported.

Healthcare professionals are asked to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Overdosage by topical application of Bacitracin is unlikely because of the limited transcutaneous absorption.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Neomycin is bactericidal for many gram-positive and gram-negative organisms. It is an aminoglycoside antibiotic which inhibits protein synthesis by binding with ribosomal RNA and causing misreading of the bacterial genetic code.
Polymyxin B is bactericidal for a variety of gram-negative organisms. It increases the permeability of the bacterial cell membrane by interacting with the phospholipid components of the membrane.

Bacitracin is bactericidal for a variety of gram-positive and gram-negative organisms. It interferes with bacterial cell wall synthesis by inhibiting the regeneration of phospholipid receptors involved in peptidoglycan synthesis.

5.2 Pharmacokinetic properties

Absorption

Neomycin—Although not absorbed through intact skin, topical neomycin is readily absorbed through large denuded, burned, or granulating areas. {13}

Polymyxin B; bacitracin—Neither polymyxin B nor bacitracin appears to be significantly absorbed following topical application to intact or damaged skin or to mucous membranes.

5.3 Preclinical safety data

No relevant data

6. Pharmaceutical particulars

6.1 List of excipients

Light Liquid paraffin BP
White Soft Paraffin BP

6.2 Incompatibilities

No incompatibilities have been identified.

6.3 Shelf life

36 Months

Discard within ONE MONTH of first opening the tube.

6.4 Special precautions for storage:

Store below 30℃

6.5 Nature and contents of the container

Aluminium tube in a carton.

6.6 Special precautions for disposal and other handling:

No special instructions needed

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:

Unisel Pharma(K)
P.O. Box 39356 00623 Nairobi

Manufacturing site address:

Aurochem Laboratories (India) Pvt. Ltd.
08, Palghar Taluka Industrial Co.-op. Estate Ltd. Palghar – 401 404,
Tel No.:0252-552332,
0252-554720
District Thane,
Maharashtra, INDIA.

Local Technical Representative:

Harleys ltd-nairobi

8. Marketing authorization number
CTD9184

9. Date of first registration
23/05/2022

10. Date of revision of the text:
15/09/2023

11. Dosimetry:
Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals:
Not Applicable