

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: Triderlin

Product name: Triple Antibiotic Pain Relief Ointment

Strength: Bacitracin Zinc 500IU, Polymyxin B Sulfate 10000IU, Neomycin 3.5mg, Pramoxine hydrochloride 10mg.

Pharmaceutical: Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant

Bacitracin Zinc , Polymyxin B Sulfate, Neomycin , Pramoxine hydrochloride

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Bacitracin Zinc 500IU, Polymyxin B Sulfate 10000IU, Neomycin 3.5mg and Pramoxine hydrochloride 10mg

3. PHARMACEUTICAL FORM

Topical Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Triple Antibiotic Pain Relief Ointment first aid to help prevent infection in minor: cuts, scrapes, burns.

4.2 Posology/Dosage and method of administration

Adults (including elderly) and children:

Clean the affected area and dry thoroughly. 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

Administration:

Cutaneous use.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction in the antibacterial

activity and potential loss of stability of the Neomycin Sulfate in the ointment.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

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

Ask a doctor before use if you have

deep or puncture wounds

animal bites

serious burns

Stop use and ask a doctor if

condition persists or gets worse

condition persists for more than 7 days

condition clears up and occurs again within a few days

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.

4.5 Interaction with other drug products and other forms of interaction

It is not likely that other drugs taken orally or injected will have an effect on topically applied bacitracin, neomycin, and polymyxin B. But many drugs can interact with each other.

4.6 Fertility, pregnancy and lactation

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with doctor.

It is not known if the medications in this product pass into breast milk. Consult doctor before breast-feeding.

4.7 Effects on ability to drive and use machines

Triple Antibiotic Pain Relief Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Get emergency medical help if have any of these signs of an allergic reaction: hives; difficult breathing; swelling of face, lips, tongue, or throat.

A rare but serious side effect of neomycin is hearing loss, which has occurred in people using other forms of neomycin. It is unlikely that absorb enough of this medicine through skin to cause this effect. Call doctor at once if notice any changes in r hearing.

Call doctor at once if have severe redness or irritation, swelling, pus, oozing, or other signs of infection.

Common side effects may include:

mild itching or rash; or

minor skin irritation after using the medicine.

4.9 Overdose

An overdose of bacitracin, neomycin, and polymyxin B topical is not expected to be dangerous.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of Action

Neomycin: Antibiotic; inhibits production of proline in bacteria resulting in cell death .Neomycin is highly effective when used in topical ointments to treat bacterial skin infections. Neomycin has excellent activity against gram-negative bacteria, and has partial activity against gram-positive bacteria.

Polymyxin B: Antibiotic; increases permeability of bacterial cell wall membranes resulting in cell lysis.

Polymyxin B is a powerful lipopeptide antibiotic that is primarily used for resistant gram-negative skin infections. It has a bactericidal action against almost all gram-negative bacterium. Polymyxin B sulfate is a strongly cationic cyclic polypeptide antibiotic that is derived from fermentation of *Bacillus polymyxin*. It is a mixture of B1 and B2 sulfate. The product has been used clinically to treat infections of the urinary tract, meninges and blood stream caused by susceptible strains of *Pseudomonas aeruginosa*. It also has uses studying multidrug-resistant pathogens, as an immobilized agent for removal of endotoxins, and to induce pore formation in the membranes of cortex cells from excised sorghum roots.

Bacitracin: Antibiotic; bactericidal or bacteriostatic depending on concentratoin; inhibits bacterial cell wall

synthesis Bacitracin is effectively used as a topical medication for specific gram negative fungal or viral skin infections like streptococcus and staphylococci 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 chemical, 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.

5.2 Pharmacokinetic properties

After topical application of Triple Antibiotic Pain Relief Ointment Neomycin Sulfate is only very minimally absorbed systemically and that which is absorbed is rapidly metabolised to the antimicrobially inactive metabolite, monic acid. Penetration of Neomycin Sulfate into the deeper epidermal and dermal layers of the skin is enhanced in traumatised skin and under occlusive dressings.

5.3 Preclinical safety data

A randomized, double-blind, placebo-controlled study was performed on 465 patients who presented to a military community hospital emergency department with a traumatic wound less than 12 hours old.⁵⁵ Thirty-nine patients were excluded from the study due to study protocol violations. There were more males in the study (n=300) compared to females (n=126) but the male-to-female ratios were similar between treatment groups. Patients were instructed to change the wound dressing and apply a blinded ointment to the wound every eight hours until the return visit to the emergency department for removal of stitches. The wound depths and locations were also not statistically significant, $p=0.66$ and $p=0.89$, respectively. Wound scrubbing ($p=0.69$) and wound debridement ($p=0.67$) were also not statistically different. The study concluded the wound infection rates for bacitracin zinc ointment (5.5 percent), bacitracin zinc/neomycin/polymyxin B ointment (4.5 percent), sulfadiazine cream (12.1 percent) were lower than petrolatum ointment (17.6 percent), $p=0.0034$, and that bacitracin zinc ointment and bacitracin zinc/neomycin/polymyxin B ointment had the lowest rate of wound infection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin, White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Inner-package: Composite Tube.

Pack Size: 30g/tube, 1tube/box

Packaging Specifications (primary packaging, secondary packaging)

Packed in tube in box with 30g and printed with batch number and manufacturing date.

Packed into carton with paper boxed inside.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

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8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

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9. NAFDAC REGISTRATION NUMBER(S)