Drugfield PHARMACEUTICALS LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Neobacin® Powder

(Neomycin 5 mg/g; Bacitracin zinc 250 IU/g)

1. NAME OF THE MEDICINALPRODUCT

Neobacin® Powder (Neomycin 5 mg/g; Bacitracin zinc 250 IU/g)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each gram contains Neomycin 5 mg/g; Bacitracin zinc 250 IU/g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder

4. Clinical particulars

4.1 Therapeutic indications

Neobacin is used in surgery and dermatology as a prophylactic and therapeutically in wound infections, burns, corrosions, excoriation, and gangrene. It is also used in the treatment of impetigo, folliculitis, eczema, seborrheic dermatitis, and in dusting of wound after era and nose surgery.

4.2 Posology

Method of administration

Apply Neobacin powder to the affected area once or several times daily after the removal of debris from the affected skin.

4.3 Contraindications

The use of the product is contra-indicated in patients who have demonstrated allergic hypersensitivity to any of the ingredients of the products or the cross sensitizing substances such as Kanamycin, Gentamicin and other related antibiotics.

Neobacin powder is contra-indicated in the presence of pre-existing nerve deafness n circumstances in which significant systemic absorption could occur. It is also contra-indicated in patients with nephrotoxic problem as well as renal impairment when systemic absorption can occur.

4.4 Special warnings and precautions for use

Bacitracin & Neomycin antibiotic powder should not be used to large open wounds or to severely injured skin or on areas that exude large volumes of fluid as hard crusts may form. Since this powder contains Neomycin, it should not be used for the treatment of otitis external when the eardrum is perforated because of risk of ototoxicity.

Patients considering self-medication with a topical anti-infective for deep or puncture wounds, animal bites, or serious burns should be advised to first consult a physician. Patients using the preparations for the prevention of infection in minor skin injuries (e.g., cuts, scrapes, burns) should be advised to discontinue the topical anti-infective preparation and consult a physician if the condition persists or worsens; it should not be used for longer than 1 week unless directed by a physician.

4.5 Interaction with other medicinal products and other forms of interaction

Bacitracin Zinc: Increased risk of nephrotoxicity when used with other nephrotoxic drugs. May enhance the action of neuromuscular-blocking agents.
Neomycin Sulphate: Additive nephrotoxic and neurotoxic effect with other aminoglycosides, bacitracin, cisplatin, vancomycin, amphotericin B, polymyxin B, colistin and viomycin. Enhanced toxicity with potent diuretics. May impair the absorption of other drugs. May enhance the effect of acarbose. May enhance the effect of non-depolarising muscle relaxants.

4.6 Fertility, pregnancy and lactation

The safe use of this preparation during pregnancy & lactation has not been established. Therefore it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The side effects of Neobacin Powder are usually mild and can present as rashes, redness of the skin and skin sensitization

4.9 Overdose

If toxic symptoms develops following significant systemic absorption of the active ingredients of Neobacin Powder, treatment with the product should be stopped and patient general status, renal function and neuromuscular function should be monitored and blood levels of Neomycin Sulphate and Bactricin Zinc determined

Haemodialysis may reduce the serum level of Neomycin Sulphate

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial ATC code: D06AX05 and Antimicrobial ATC code: A07AA01

Mechanism of action:

Bacitracin inhibits bacterial cell wall synthesis and is active against many gram-positive bacteria (e.g. staphylococci, streptococci, corynebacteria and Clostridia) and some gram-negative species (e.g. Neisseria and Haemophilus influenzae). They are often found in combinations in topical preparations as broad spectrum antibacterial agents.

Neomycin, an aminoglyoside with antimicrobial spectrum similar to gentamicin, binds to the 30S subunits of the bacterial ribosome, inhibiting protein synthesis and thereby disrupting DNA synthesis. It is active against many gram negative aerobes and against some strains of staphylococci.

5.2 Pharmacokinetic properties

Absorption: Neomycin: Poorly absorbed from GI tract. Absorption may occur from peritoneum, respiratory tract, bladder, wounds and inflamed skin; increased when mucosa is damaged or inflamed. Bacitracin: Poorly absorbed from the GI tract or from intact or denuded skin, wounds or mucous membranes.
Distribution: Bacitracin: Diffuses into pleural and ascitic fluids.
Excretion: Neomycin: 97% of oral dose excreted unchanged in faeces; absorbed neomycin excreted by kidneys in active form; half life: 2-3 hr. Bacitracin: 10-40% of injected dose excreted slowly by kidney and appears in urine within 24 hr.

5.3 Preclinical safety data

Neobacin Powder by its route of administration is generally safe except when significant system absorption occurs in which case the individual components may impair the absorption of the drugs such as digoxin, methotrexate and some vitamins. The efficacy of Oral contraceptives might be reduced.

6.0 PHARMACEUTICALPARTICULARS

6.1 List of excipients

Lactose Anhydrous

Aerosil 200

6.2 Incompatibilities

None have been reported or are known

6.3 Shelf life

48 Months

6.4 Special precautions forstorage

Store below 30^{o}C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Neobacin® Powder is presented as a powdry medicament packed in a plastic pack of 5g in hardboard carton with leaflet enclosed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue Km38,
Lagos-Abeokuta Expressway
Sango-Otta, Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com