Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Bacitracin & Neomycin Aerosol powder Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Each 150 ml contains: Bacitracin Zinc 12500 IU, Neomycin Sulphate 165000 IU, Propane/Butane (25%75%) to 150 ml.
3. PHARMACEUTICAL FORM
4. Aerosol Spray

4. Clinical particulars

4.1Therapeutic indications

Bacitracin & Neomycin topical antibacterial aerosol powder spray is indicated in Dermatology: - Pyodermia epidermal (impetigo group). – Epidermocutaneous pyodermia(folloculitis)-primarily to prevent spread of infection. - Superinfections of surface wounds and burns - Bacterial dermatopathies(ecthymagangrenosum) - Prevention of pyococca lsuperinfections in case of increases risk of their occurrence(herpes simplex, herpes zoster, bites of insects). Otology: - Inflammation of external ear canal. - For prophylaxis, it is also used in surgery and otorhinolaryngology

4.2 Posology and method of administration

No data are available. Currently available data are described in Section 4.8, 5.1, & 5.2 but no recommendation on a posology can be made.

Posology: Application should be limited to a maximum of one can per day for not more than seven days.

Method of administration - Shake the aerosol container vigorously and spray the powder to the affected area once or several times daily from a distance of 20 to 25 cm. - Don't incline to an angle greater than 45 degrees - Apply sparingly. - Apply the powder spray to the affected area as a thin layer once or several times daily.

4.3 Contraindications –

Hypersensitivity to neomycin, bacitracin or other ingredients of this combination. - Perforation of the eardrum at local application to the ear canal.

4.4 Special warnings and precautions

For use Systemic absorption can occur following application over large areas (>20%), on wounds, burns or ulcerations. Since systemic absorption can occur through the skin, it should be used cautiously in patients with renal insufficiency as it may increase the hazard of nephrotoxicity and ototoxicity. - It

should be discontinued if any signs of skin irritation or hypersensitivity occur. - Aerosol container is under pressure, it contains a gas propellant. - Don't perforate or burn, even when empty. - Inflammable. - Bivatracin should be kept out of reach of children. - For external application only.

4.5 Interaction with other medicinal products and other forms of interaction

There are no reported drug interactions.

4.6 Pregnancy and Lactation

Bacitracin & Neomycin aerosol spray should be used for pregnancy and lactation only if clearly indicated and should not be used over wide areas and for prolonged periods to prevent the risk of systemic absorption associated with topical use.

4.7Effects on ability to drive and use machines: Not Relevant.

4.8Undesirable effects –

Hypersensitivity reaction to the active ingredients may occur. - Local skin irritation, swelling, itching, urticaria, contact dermatitis, super infection has been reported Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Systemic toxic effects (nephrotoxicity and ototoxicity) are unlikely to occur and may appear only after prolonged use of large doses over wide areas of the affected skin. If overdose occurs the patient should be monitored for evidence of toxicity and standard supportive treatment applied as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic group:

Bacitracin & Neomycin aerosol spray antibacterial action is provided by the overlapping spectra of Neomycin and Bacitracin .Bacitracin is a polypeptide antibiotic which inhibits bacterial cell wall synthesis. It is especially active against gram-positive and some gram-negative microorganisms. It was found to target Gram-positive organisms, especially those that cause skin infections including:Staphylococcus, Staphylococcus epidermidis, Streptococcus pyogenes. Neomycin is an aminoglycoside antibiotic that inhibits bacterial protein synthesis and has excellent activity against Gram-negative bacteria, and is partially effective against Gram-positive bacteria. Bivatracin is used for topical treatment of most infections caused by grampositive and gram-negative bacteria, it is practically not absorbed, and therefore it has no systemic action.

5.2 Pharmacokinetic properties –

When applied topically, no systemic absorption occurs. - Systemic absorption can occur only following application over large areas (>20%), on wounds, burns or ulcerations 5.3Preclinical safety data Non

6. **PHARMACEUTICAL PARTICULARS**

6.1List of excipients Aerosil 200 Talc Powder Propane/Butane (25%75%)

6.2 Incompatibilities

No incompatible materials are found between the drug substance and excipients. – Concerning the excipients: 1. Talc Powder is incompatible with quaternary ammonium compounds. 2. Aerosil 200 is incompatible with diethylstilbesterol preparations.

6.3 Shelf life: 3 Years

6.4Special precautions for storage –

Store Bacitracin & Neomycin spray at a temperature below 30 ℃ - Keep the medicine from freezing. - Keep the container away from direct heat sources. - Keep out of reach of children.

6.5 **Nature and contents of container** –

Pressurized continuous valve topical spray containing white to yellowish white powder. - One Box containing one aluminum can spray of 150 ml aerosol powder and inner leaflet.

6.6 Special precautions for disposal –

After use clean the valve by turning the aerosol container upside down and blow the valve by short pressing. - Occasional agglomeration of powder in the valve can be cleaned with a hypodermic needle no (15-17).

7. Marketing Authourization Holder

Smart Way Pharma Ltd

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