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SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. GENERIC NAME

NORBATRIN POWDER (Neomycin Sulphate and Bacitracin Zinc Powder)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Bacitracin Zinc BP equivalent to Bacitracin 250 units
Neomycin Sulphate BP equivalent to Neomycin 3300 units

3. DOSAGE FORM AND STRENGTH

Powder for topical use.

Each gram contains:

Bacitracin Zinc BP equivalent to Bacitracin 250 units
Neomycin Sulphate BP equivalent to Neomycin 3300 units

4. CLINICAL PARTICULARS

4. 1 Therapeutic Indications

NORBATRIN POWDER is indicated in conditions where superficial bacterial skininfection 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.

The use of *NORBATRIN POWDER* does not exclude concomitant systemic therapy withantibiotics where appropriate (*see 4.4 Special Warnings and Precautions for Use).*

Posology and Method of Administration

NORBATRIN POWDER is for topical skin administration only.

Populations

- *Adults*

Following any necessary removal of debris, such as pus, crusts, etc. from the affected area, a thin layer of powder should be applied one to three times daily, depending on the clinical condition. Treatment should not be continued for more than seven days without medical supervision.

- *Children*

NORBATRIN POWDER is suitable for use in children (two years and over) at the same dose as adults. A possibility of increased absorption exists in very young children thus the product is not recommended for use in neonates and infants (less than two years) *(see 4.3 Contraindications and 4.4 Special Warnings and Precautions for Use).*

- *Elderly*

NORBATRIN POWDER is suitable for use in the elderly. Caution should be exercised incases where a decrease in renal function exists, and significant systemic absorption of neomycin sulphate may occur *(see 4.4 Special Warnings and Precautions for Use).*

- *Renal Impairment*

Dosage should be reduced in patients with reduced renal function *(see 4.4 Special Warnings and Precautions for Use).*

Contraindications

- The use of *NORBATRIN POWDER* is contraindicated in patients who have demonstrated allergic hypersensitivity to any of the ingredients of the product or to cross- sensitising substances such as framycetin, kanamycin, gentamycin and other related antibiotics.
- Due to the known ototoxic and nephrotoxic potential of neomycin sulphate the use of *NORBATRIN POWDER* in large quantities or on large areas for prolonged periodsof time is not recommended in circumstances where significant systemic absorption may occur.
- A possibility of increased absorption exists in very young children thus *NORBATRIN POWDER* is not recommended for use in neonates and infants (less than 2 years).In neonates and infants, absorption by immature skin may be enhanced and renal function may be immature.
- The presence of pre-existing nerve deafness is a contraindication to the use of *NORBATRIN POWDER* or any topical aminoglycoside in circumstances where significant systemic absorption could occur.
- *NORBATRIN POWDER* should not be used to treat otitis externa in the presenceof a perforated tympanic membrane because of the risk of ototoxicity.

Special Warnings and Precautions for Use

As with other antibacterial preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is unlikely to occur with topically applied antibiotics, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately, and the patient investigated further.

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; neomycin sulphate and bacitracin zinc have nephrotoxic potential .

In renal impairment the plasma clearance of neomycin is reduced *(see 4.2 Posology and Method of Administration).*

The concurrent use of other aminoglycoside antibiotics is not recommended in circumstances where significant systemic absorption of neomycin sulphate could occur following topical application.

Avoid introduction of *NORBATRIN POWDER* into the eyes. If *NORBATRIN POWDER* is accidentally introduced into the eye, the eye should be rinsed thoroughlywith cold water.

NORBATRIN POWDER should be kept out of reach of children.

Drug Interactions

Following significant systemic absorption, neomycin sulphate canintensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

However, the neuromuscular blocking activity of neomycin sulphate isunlikely to present a hazard during use of *NORBATRIN POWDER*.

Use in Special Populations

- *Children*

NORBATRIN POWDER is suitable for use in children (two years and over) at the samedose as adults. A possibility of increased absorption exists in very young children, thus the product is not recommended for use in neonates and infants (less than two years) *(see 4.3 Contraindications and 4.4 Special Warnings and Precautions for Use).*

- *Elderly*

NORBATRIN POWDER is suitable for use in the elderly. Caution should be exercised incases where a decrease in renal function exists, and significant systemic absorption of neomycin sulphate may occur *(see 4.4 Special Warnings and Precautions for Use).*

- *Renal Impairment*

Dosage should be reduced in patients with reduced renal function *(see 4.4 Special Warnings and Precautions for Use).*

- *Pregnancy and Lactation*

There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of *NORBATRIN POWDER*is not recommended in pregnancy and lactation.

Effects on Ability to Drive and Use Machines

None reported.

Undesirable Effects

The incidence of allergic hypersensitivity reactions to neomycin sulphate in the general population is low. There is, however, an increased incidence of hypersensitivity to neomycin in certain selected groups of patients in dermatological practice particularly those with venous stasis eczema and ulceration.

Allergic hypersensitivity to neomycin sulphate following topical application may manifest itself as a reddening and scaling of the affected skin, as an eczematous exacerbation of the lesion or as a failure of the lesion to heal.

Allergic hypersensitivity reactions following topical application of bacitracin zinc is rare events but have been reported.

Anaphylactic reactions following the topical administration of bacitracin zinc have been reported; but these are rare occurrences.

Post marketing Data

Immune System Disorder

Rare: Application site hypersensitivity

General Disorders and Administration Site Conditions

Rare: Application site reactions including pain, erythema, oedema, pruritis and exacerbation of underlying skin conditions.

Overdose

Symptoms and Signs

Following accidental ingestion of *NORBATRIN POWDER,* minimal absorption isexpected.

No specific symptoms or signs have been associated with excessive use of *NORBATRIN POWDER*. However, consideration should be given to significant systemic absorption*(see 4.4 Special Warnings and Precautions for Use).*

Treatment

Use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulphate and bacitracin zinc should also bedetermined, and haemodialysis may reduce the serum level of neomycin sulphate.

5. PHARMACOLOGICAL PROPERTIES

Mechanism of action

Neomycin sulphate: Neomycin is an aminoglycoside antibiotic which acts by binding to a specific protein on the 30S subunit of the microbial ribosome, leading to faulty alignment or recognition with respect to messenger RNA and probably t-RNA during initiation of microbial peptide chain formation. The messenger RNA is misread on the recognition region of the ribosome, resulting in the wrong amino acid being inserted into the peptide. The affected ribosomes are released and may be able to re-initiate and repeat the process, leading to increased proportions of non-functional peptide chains.

Bacitracin Zinc: Bacitracin is a mixture of polypeptides derived from Bacillus subtilis. It inhibits growth of bacteria primarily by preventing the formation of peptidoglycan chains needed for cell wall synthesis and by altering membrane permeability

Pharmacodynamic Properties

NORBATRIN POWDER is active *in vitro* against a wide range of bacterial pathogensfound in superficial dermatological infections. Susceptible organisms include:

Gram-positive:

- *Staphylococcus* spp. including *Staphylococcus aureus*
- *Streptococcus* spp. including *Streptococcus pyogenes*.

Gram-negative:

- *Enterobacter* spp.
- *Escherichia* spp.
- *Haemophilus* spp.
- *Klebsiella* spp.
- *Neisseria* spp.
- *Proteus* spp.
- *Pseudomonas* spp. including *Pseudomonas aeruginosa*.

Pharmacokinetic Properties

Neomycin sulphate: Absorption through skin is limited.

6. NONCLINICAL PROPERTIES

No data.

7. DESCRIPTION

Each gram contains:

Bacitracin Zinc BP equivalent to Bacitracin 250 units

Neomycin Sulphate BP equivalent to Neomycin 3300 units

List of Excipients

Starch (Sanitised)PHARMACEUTICAL PARTICULARS

Incompatibilities

No incompatibilities have been identified.

Shelf-Life

The expiry date is indicated on the label and packaging.

Packaging Information

HDPE bottle.

Storage and Handling Information

Store at temperature not exceeding 30ºC, in a dry place.
Keep out of reach of children.
For external use only.
Keep container tightly closed.

8. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or their patient's caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *NORBATRIN POWDER*. Patients (and/or their patient's caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

9. DETAILS OF MANUFACTURER

M/S MARINE LIFESCIENCES
PLOT NO. 30 PHASE III
(EXT.) HPSIDC, BADDI,
173205, H.P.

10. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing Licence number is indicated on the label and packaging.

11. DATE OF REVISION

08-DEC-2022