SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Neomycin Sulphate Tablets 500 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label claim

Each uncoated tablet contains:

Neomycin Sulpahte B.P. 500 mg

List of Excipients:

Cross Carmollouse sodium, Lactose, Magnesium Stearate, Maize Starch, Microcrystalline cellulose powder, Polyvinyl Pyrrolidone (PVP-K 30), Sodium Bi Sulphite, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Starch Glycolate, Talcum.

3. PHARMACEUTICAL FORM

Off white coloured, circular, flat, bivelled, uncoated tablets with cross mark on one side & "NEOMYCIN-500" embossed on other side of each tablet.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Neomycin tablet (Neomycin sulphate BP) is indicated for pre-operative sterilisation of the bowel and may be useful in the treatment of impending hepatic coma, including portal systemic encephalopathy.

4.2 Posology and method of administration

Pre-operative sterilisation of the bowel.

Adults: 2 tablets every hour for 4 hours; then 2 tablets every 4 hours for two or three days before the operation.

Children over 12 years: 2 tablets every 4 hours for 2 or 3 days before the operation.

Children from 6 to 12 years: ½ to 1 tablet every 4 hours for 2 or 3 days before the operation.

For practical reasons, use of the tablets in children under 6 years is not recommended.

In hepatic coma, the adult dose is 4-12 gm/day in divided doses for a period of 5-7 days, whilst for children, 50-100mg/kg/day in divided doses appears appropriate. Chronic hepatic insufficiency may require up to 4gm/day over an indefinite period.

The elderly dose is the same as for adults.

Method of administration

For oral administration.

4.3 Contraindications

Neomycin tablets should not be given when intestinal obstruction is present.

Hypersensitivity to aminoglycosides.

Infants under 1 year.

Myasthenia gravis

4.4 Special warnings and precautions for use

The absorption of neomycin is poor from the alimentary tract, with about 97% of an orally administered dose being excreted unchanged in the faeces. Impaired G.I. motility however may increase absorption of the drug and it is therefore possible, as with other broad spectrum antibiotics, that prolonged therapy could result in ototoxicity and nephrotoxicity, particularly in patients with a degree of renal failure. In such patients, and infants and the elderly, it is generally desirable to determine dosage requirements of aminoglycosides by individual monitoring. Some authorities consider that monitoring is also important in obese patients and those with cystic fibrosis.

Impaired hepatic function or auditory function, bacteraemia, fever, and possibly exposure to loud noises have been reported to increase the risk of ototoxicity, while volume depletion or hypotension, liver disease, or female sex have reported as additional risk factors for nephrotoxicity. Regular assessment of auditory, vestibular and renal function is particularly necessary in patients with additional risk factors.

When used as an adjunct in the management of hepatic coma, care should be taken that administration is of the minimal period necessary, since prolonged exposure to the drug may result in malabsorption.

Neomycin should be used with caution in patients with neuromuscular disorders and Parkinsonism.

There is almost complete cross-resistance between neomycin, kanamycin, paromomycin and framycetin. Cross-resistance with gentamicin has also been reported.

Since prolonged therapy may result in the overgrowth of non-sensitive organisms, treatment should not be continued longer than necessary to prevent superinfection due to the over growth of non-sensitive organisms.

4.5 Interaction with other medicinal products and other forms of interaction

Neomycin may impair absorption of other drugs including phenoxymethylpenicillin, digoxin, methotrexate and some vitamins. Aminoglycosides exhibit synergistic activity with a number of beta lactams, but aminoglycoside activity was reported to be diminished in a few patients with severe renal impairment.

Care should be taken when considering the use of neomycin concurrently with drugs with a potential to cause nephrotoxicity (including other aminoglycosides, some of the cephalosporins, amphotericin, ciclosporin, capreomycin, polymixins, platinum compounds, teicoplanin and vancomycin) or

ototoxicity (including loop diuretics, capreomycin, teicoplanin, vancomycin and possibly platinum compounds).

The effect of non-depolarising muscle relaxants may be enhanced by aminoglycosides. Care is required if other drugs with a neuromuscular blocking action, including botulinum toxic, are given concomitantly. Care is required when patients being treated with aminoglycosides are to receive a general anaesthetic or opioids in order to avoid the possible neuromuscular side-effects provoking severe respiratory depression.

The effect of the parasympathomimetic drugs neostigmine and pyridostigmine, may be antagonised by aminoglycosides.

The hypoglycaemic effect of acarbose may be enhanced by neomycin and the severity of gastrointestinal side effects increased.

Aminoglycosides may increase the risk of hypocalcaemia in patients receiving bisphosphonates.

Experience in anticoagulant clinics suggests that INR (International Normalised Ratio) may be altered by antibacterials such as neomycin given for local action on the gut.

The efficacy of oral contraceptives may be reduced with broad spectrum antibiotics.

Oral typhoid vaccine is inactivated by concomitant antibiotic administration

4.6 Fertility, pregnancy and lactation

The use of neomycin in pregnancy is not recommended unless the benefits outweigh the potential risks.

There are no reports linking the use of neomycin to congenital defects. However, small amounts of the drug are absorbed when given orally and neomycin and other aminoglycosides may have harmful effects on the foetus following oral absorption during pregnancy.

In some circumstances neomycin may enter the breast milk of lactating mothers. There is little risk of ototoxicity in the infant, but abnormal development of the gut flora may occur. The use of neomycin in lactating mothers is not recommended unless the benefits outweigh the potential risks.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Nausea, vomiting, diarrhoea, increased salivation, stomatitis, nephrotoxicity, ototoxicity, rise in serum levels of hepatic enzymes and bilirubin, blood dyscrasias, haemolytic anaemia, confusion, paraesthesia, disorientation, nystagmus, hypersensitivity reactions including dermatitis, pruritus, drug fever and anaphylaxis.

Cross-sensitivity with other aminoglycosides may occur.

Malabsorption syndrome with steatorrhoea and diarrhoea, which can be severe, may be caused by prolonged oral therapy.

Superinfection may occur, especially with prolonged oral treatment.

Electrolyte disturbances (notably hypomagnesaemia but also hypocalcaemia and hypokalaemia) have occurred with other aminoglycosides.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

In overdose, exacerbation of the adverse events reported for neomycin (nausea, diarrhoea nephrotoxicity, ototoxicity etc.) is expected.

Monitor renal and auditory function. If these are impaired, haemodialysis is indicated.

Prolonged assisted ventilation may also be required

5. Pharmacological properties

5.1 Pharmacodynamic properties

Neomycin is an aminoglycoside antibiotic.

Neomycin acts by binding to polysomes, inhibiting protein synthesis and generating errors in the transcription of the genetic code.

5.2 Pharmacokinetic properties

The absorption of neomycin from the alimentary tract is poor: Only 3% of an oral dose is absorbed, neomycin is rapidly excreted by the kidneys in the unchanged form. The plasma half-life in healthy adults is approximately 2-3 hours. Oral doses of 3g produce peak plasma concentrations of up to 4 μg/ml.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cross Carmellouse sodium, Lactose, Magnesium Stearate, Maize Starch, Microcrystalline cellulose powder, Polyvinyl Pyrrolidone (PVP-K 30), Sodium Bi Sulphite, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Starch Glycolate, Talcum.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a cool dark place below 30ºC & keep out of reach of children.

6.5 Nature and contents of container

100 Tablets.

6.6 Instructions for use and handling and disposal

No special requirements.

7. Marketing authorization holder

GREAT TIMEC PHARMA COMPANY LIMITED

19B, Niger Bridge head, Housing Estate,

Fegge, Onitsha, Anambra, Nigeria

Manufactured by:

NEM LABORATORIES PRIVATE LTD.,

133, Krishna Indl. Estate,

Navghar, Vasai Road (E),

Dist. Thane - 401 210. INDIA.

E-mail: nemlabs@gmail.com

8. Number(s) in the national register of finished pharmaceutical products

NAFDAC REGN. NO.: B4-0630

9. Date of first authorization/renewal of the authorization

30th Apr. 2013

10. Date of revision of the text

29th Apr. 2018