NEON

(CEFTRIAXONE)

INJECTION

Composition:

Each vial of neon 250mg IV / IM contains:

Ceftriaxone Sodium (USP) eq. to Ceftriaxone 250mg

Each vial of neon 500mg IV / IM contains:

Ceftriaxone Sodium (USP) eq. to Ceftriaxone 500mg

Each vial of neon 1g IV contains:

Ceftriaxone Sodium (USP) eq. to Ceftriaxone 1g

Each vial of neon 2g IV contains:

Ceftriaxone Sodium (USP) eq. to Ceftriaxone 2g

INDICATIONS

Cephalosporins (Ceftriaxone Sodium) are antibiotics used to treat a wide variety of bacterial infections, such as respiratory tract infections, skin infections and urinary tract infections.

- Infections caused by pathogens sensitive to Ceftriaxone.
- Sepsis.
- Meningitis
- Abdominal infection (Peritonitis, infections of the biliary and gastro intestinal tracts).
- Infections of the bones, joints, soft tissues, skin and wounds.
- Infections in patients with impaired defense mechanisms.
- Renal and urinary tract infections.
- Respiratory tract infections, particularly pneumonia and ear, nose and throat infections.
- Genital infections including gonorrhoea.
- Preoperative prophylaxis of infections.

ANTIMICROBIAL ACTION

Neon (Ceftriaxone) inhibits cell wall synthesis resulting in antimicrobial action. Ceftriaxone is highly stable to hydrolysis by most beta lactamases and has greater activity against gram negative bacteria than 1st Or 2nd generation cephalosporins.

Neon (Ceftriaxone) is active against the following organisms including

GRAM-POSITIVE AEROBES

- Staphylococcus aureus (including penicillinase-producing strains)
- Staphylococcus epidermidis
- Streptococcus pneumoniae
- Streptococcus group A (Str. Pyogenes)
- Streptococcus group B (Str. Agatactiae)
- Streptococcus viridans
- Streptococcus bovis

Note: Methicillin - resistant Staphylococcus spp. are resistant to cephalosporins, including Ceftriaxone.

Most strains of Enterococci (e.g. streptococcus faecalis) are resistant.

GRAM-NEGATIVE AEROBES

- Aeromonas spp.
- Alcaligenes spp.
- Branhamella catarrhalis (3-lactamase negative and positive)
- Citrobacter spp.
- Enterobacter spp. (some strains are resistant)
- Escherichia coli Haemophilus ducreyi
- Haemophilus influenzae (including penicillinase producing strains)
- Haemophilus para-Influenzae
- Klebsiella spp. (including kipneumoniae)
- Moraxella spp.
- Morganella morganii
- Neisseria gonorrhoea (including penicillinase- producing strains)
- Neisseria meningitides
- Plesiomonas shigelloides
- Proteus mirabills Proteus vulgaris
- Providencia spp.
- Pseudomonas aeruginosa (some strains are resistant)
- Salmonella spp. Including S. typhi)
- Serratia spp. (including V. Marcescens)
- Shigella spp.
- Vibrio spp. (including V. Cholerae)
- Yersinia spp. (including Y. Enterocolitica)

PHARMACOKINETICS

Neon (Ceftriaxone) demonstrates non-linear dose dependent pharmacokinetics because of its protein binding. About 85-95% is bound to plasma protein depending on plasma concentration of Ceftriaxone. The plasma half-life is not dependent on the dose and varies between 5-9 hours, it is prolonged in neonates. Half-life does not change in patients with moderate renal Impairment but may be prolonged in severe renal failure especially when there is also hepatic failure. Neon (Ceftriaxone) is widely distributed in body tissues and fluids. Therapeutic concentrations are achieved in the cerebrospinal fluid when meninges are inflamed.

It crosses the placenta and is excreted in the breast milk in low concentrations and High concentrations are achieved in bile. About 40-65% of dose is excreted unchanged in the urine the remainder is excreted in the bile and is ultimately found in the faeces as unchanged drug and microbiologically in active compounds.

DIRECTION FOR USE

Reconstituted solutions retain their physical and chemical stability for six hours at room temperature (or 24 hours at 5°C) however; the solutions should be used immediately after preparation. They range in colour from pale yellow to amber, depending on the concentration and the length of storage. This characteristic of the active ingredient is of no significance for the efficacy or tolerance of the drug.

INTRAMUSCULAR INJECTION

250mg and 500mg should be dissolved in 2ml of 1% lignocaine hydrochloride solution. Dose greater than 1gm should be divided and injected more than one site.

INTRAVENOUS INJECTION
250mg and 500mg should be dissolved in 5ml of sterile water for injection, 1g should be dissolved in 10ml of sterile water for injection and 2g should be dissolved in 20ml of sterile water for injection (2 ampoules of 10ml each). The injection should be administered over 2 -4 minutes, directly into the vein or via the tubing of an intravenous infusion.
Injection reconstituted with lidocaine should not be used intravenously.

DOSAGE AND ADMINISTRATIONS
Doses are expressed in terms of equivalent amount of Ceftriaxone.

ADULTS AND CHILDREN OVER 12 YEARS
The usual adult dose is 1 to 2 gm daily as a single dose or in divided doses twice a day. In severe cases 2 to 4 gm daily normally as a single dose every 24 hours.

GONORRHOEA
A single intramuscular dose of 250mg is recommended for the treatment of gonorrhoea in adults.

IMPAIRED RENAL & HEPATIC FUNCTION
A reduction in dose is recommended in patients with severe renal failure and in those with both impaired renal failure and hepatic function. Plasma concentrations should be monitored in such patients.

NEONATES (UP TO TWO WEEKS)
A daily dose of 20-50 mg / kg body weight not exceeds 50 mg/kg on account of immaturity of the infants' enzyme system. It is necessary to differentiate between premature and infants.

CHILDREN (THREE WEEKS TO TWELVE YEARS)
Children should be given 50-75 mg/kg body weight daily in two divided doses the total daily dose should not exceed 2 gm for the treatment of the meningitis in children, Neon (ceftriaxone) may be given in dose of 100mg per kg body weight, daily in two divided doses some-times with a loading dose of 75 mg per kg body weight, the total daily dose should not exceed 4gm. The daily dose may be administered once a day (or in equally divided doses every 12 hours). The usual duration of therapy is 7 to 14 days. For children with body weight of 50kg or more the usual adult dosage should be used.

USE IN ELDERLY
The recommended dosages for adults do not require modification in the case of elderly patients provided that renal and hepatic functions are satisfactory.

CONTRAINDICATIONS
Neon (Ceftriaxone) is contraindicated in patients who are sensitive to cephalosporin antibiotics. Care should be taken while administering to nursing mothers. Neon (ceftriaxone) should not be given during pregnancy.

SIDE EFFECTS
Side effects are mild and transient in nature when they happen they should be treated symptomatically. The most common side effects are gastrointestinal disturbances (loose stools, diarrhoea, nausea, vomiting, stomatitis, glossitis, cutaneous reaction include maculopapular rash, pruritus, urticaria, oedema and erythema multiforme, haematological reaction include anaemia, leucopenia, neutropenia, thrombocytopenia, eosinophilia, agranulocytosis, headache, dizziness, drug fever and transient elevations in liver function test have been reported in a few cases.

INSTRUCTIONS
Store at 15-30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION
Each Intramuscular Neon vial of 250mg and 500mg (containing Ceftriaxone sodium eq. to 250mg and 500mg Ceftriaxone respectively) is supplied with 1% lignocaine Hydrochloride solution.
Each Intravenous Neon vial of 250mg, 500mg, 1g and 2g (containing Ceftriaxone sodium eq. to 250mg , 500mg , 1g and 2g Ceftriaxone respectively) is supplied with ampoule of sterile water for injection.

نی آن انجیکشن
(سیفٹرائی ایگزون)

ہدایات: دوا کو 15-30° سینٹی گریڈ پر رکھیں ۔ گرمی، روشنی اور نمی سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دُور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:
STANDPHARM PAKISTAN (PVT) LTD
20 Km Ferozepur Road Lahore, Pakistan.

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