Pharmacodynamics:

Ceftriaxone is a broad-spectrum cephalosporin antibiotic. It is active against a wide range of Gram-positive and Gram-negative bacteria, including many that are resistant to other antibiotics. Ceftriaxone is eliminated mainly as unchanged drug, with about 20% of the dose excreted in the feces and 80% of the dose excreted in the urine; over 90% of the dose is excreted within 24 hours. The plasma clearance is 10-22 ml/min. The renal clearance is 5-12 ml/min. A notable feature of ceftriaxone is its long plasma elimination half-life of approximately 10 hours, which makes it suitable for once daily dosing for the treatment of infections.

Pharmacokinetics:

Ceftriaxone is not significantly affected by the dose, the route of administration, or by repeated administration. Pharmacokinetic studies in special clinical situations: In the first week of life, 80% of the dose is excreted in the urine; over 12 hours, but not more than 2 g / day. In severe infections at other sites - at a dose of 25 - 37.5 mg / kg every 12 hours, but not more than 2 g / day. Off-label use may include the administration of IM - 50 mg / kg of body weight, but not more than 1 g. In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone provided liver function is intact. Only in cases of pre-terminal renal failure (creatinine clearance <10 ml/min) should the daily dosage be limited to 2g or less. Injection should be given slowly before use. To prepare the solution for injection, 0.5 g dissolved in 2 ml and 1 g of product - 3.5 ml of 1% lidocaine. It is recommended that not more than 1 g per one buttock. To prepare the solution for IV injection, 0.5 g dissolved in 5 ml and 1 g of product - 10 ml of sterile water for injection. Injection solution administered IV (slowly) for 24 hours.

To prepare the solution for IV infusion of 2 g of the drug dissolved in 1/5 of one of the following solutions containing calcium: 0.9% sodium chloride, 5 - 10% dextrose (glucose), levulose 5% solution. Preparation of 50 mg / kg and more to be administered IV drip for 30 min.

Contraindications:

Hypersensitivity to the drug;
Hypersensitivity to other cephalosporin’s, penicillin’s, carbapenem’s;
Contraindications of lidocaine must be excluded before intramuscular injection of ceftriaxone when lidocaine is used as a solvent.

Warnings and Precautions:

With caution should be prescribed for newborns with hypothyroidism, premature babies and patients with renal or hepatic failure, elderly patients receiving inhalation anaesthesia, patients with low vitamin K levels or those with malnourished patients or those with low vitamin K levels and also in patients receiving parenteral corticosteroids and these antibiotics have been recomended. Anaphylactic shock requires immediate counter measures.

Safety and effectiveness of Speycef in neonates, infants and children have been established for the dosages. As infants and children have different renal function, renal function data obtained in neonates have confirmed this finding. Ceftriaxone should therefore not be used in neonates (especially premature) at risk of developing bilirubin encephalopathy.

Regular blood counts (haemoglobin, erythrocyte, leucocyte and platelet count) are advisable in the event of prolongation of prothrombin time should be carried out during treatment.

Cephalosporins may cause bleeding due to hypoprothrombinemia and should be used with caution in patients with renal or hepatic impairment, malnourished patients or those with low vitamin K levels and also in patients receiving parenteral corticosteroids before use. There is no specific antidote. Treatment is symptomatic.

Dosage Forms and Packaging Available

1X10 20 ml glass vial in an outer Carton with instruction for use.

Storage:

Keep in dry place protected from light at a temperature below 30°C. Keep out of reach of children.

Shelf life:

2 years. Do not use after expiry date.

Distribution Condition:

Prescription only medicine (POM).