Anhui Chengshi Pharmaceutical Co.,Ltd
安徽城市药业股份有限公司

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1-Name of the Medicinal Product ： Ceftriaxone Sodium for Injection 1g

1.1 Product Name: Ceftriaxone Sodium for Injection

1.2 Strength: 1g

1.3 Pharmaceutical Dosage Form: powder for injection

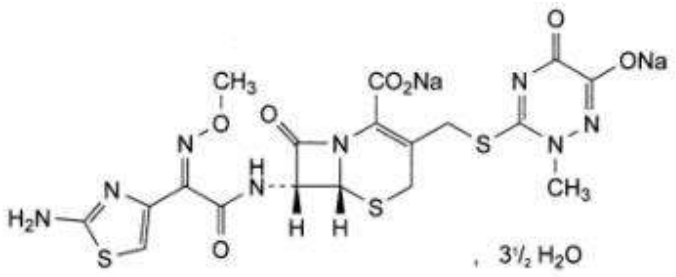
2-Quality and Quantitative Composition ：

2.1 Qualitative Declaration
The active substance of the Ceftriaxone Sodium for Injection is Ceftriaxone Sodium.

Ceftriaxone Sodium：Almost white or yellowish, slightly hygroscopic crystalline powder.

The molecular formula of Ceftriaxone Sodium: $C_{18}H_{16}N_8Na_2O_7S_3,3^1/_2\ H_2O$

The structural formula of Ceftriaxone Sodium :



The molecular weight of Ceftriaxone Sodium : 662

The CAS number of Ceftriaxone Sodium : 104376-79-6

2.2 Quantitative Declaration

Ceftriaxone Sodium for Injection 1g

Dosage form：powder for injection

Concentration：1g

Product description：1.19g of almost white or yellowish, slightly hygroscopic crystalline powder is filled in the glass vial.

Ingredients	Quantity per vial	Function of ingredients
Ceftriaxone Sodium	1.19g（equivalent to Ceftriaxone 1g）	Active substance

3-Pharmaceutical Form ：

Dosage form：powder for injection
1.19g of white or almost white crystalline powder is filled in the glass vial.

4-Clinical Particulars

4.1 Therapeutic indications

It is used for the prevention of lower respiratory tract infection, urinary tract infection, biliary tract infection, abdominal cavity infection, pelvic cavity infection, skin soft tissue infection, bone and joint infection, septicemia, meningitis and operative infection caused by sensitive pathogens. A single dose of this product can treat simple gonorrhea.

4.2 Posology and method of administration

- Recommended doses ：

The drug is administered intramuscular or intravenously.
1. Preparation of intramuscular injection solution: 3.6ml sterilized water for injection, sodium chloride injection, 5% glucose injection or 1% lidocaine hydrochloride were added into 1g bottle to make a solution containing 250mg ceftriaxone per 1mL.
2. Preparation of intravenous administration solution: add 9.6ml of the above-mentioned diluent (except lidocaine) into a 1g bottle to make a solution containing 100mg ceftriaxone per 1ml, and then dilute it with 5% glucose injection or sodium chloride injection 100-250 ml before intravenous infusion.
Adults usually use intramuscular or intravenous infusion, 1 ~ 2g every 24 hours (1 ~ 2 doses) or 0.5 ~ 1g every 12 hours (0.5 ~ 1 doses). The maximum dose is 4g (4 doses) per day. The course of treatment lasted from 7 to 14 days.
Children often use intravenous drip, according to body weight 20 ~ 80mg/kg a day. Adult dose for children over 12 years of age.

The recommended dose for gonorrhea is a single dose of 0.25g intramuscular injection (0.25 dose).

4.3 Contraindications

1. Allergic to cephalosporin antibiotics is prohibited.
2. This product can not be used in hartman's and Ringer's solutions containing calcium. Concomitant administration of this product with calcium-containing agents or calcium-containing products may result in adverse events with fatal outcomes.

4.4 Special warning and precautions for use

1. Allergy test should be conducted before administration.
2. Cross-allergic reaction: People who are allergic to one cephalosporin or cephamycin may also be allergic to other cephalosporin or cephamycin. People who are allergic to penicillins, penicillin derivatives, or penicillamine may also be allergic to cephalosporin or cephalomycin. When cephalosporin was used in patients allergic to penicillin, 5% ~ 10% of patients had allergic reactions. When the immune response was measured, cephalosporin allergy was found in 20% of patients allergic to penicillin.
3. Patients with penicillin allergy should fully weigh the advantages and disadvantages of this product according to the patient's situation. There is penicillin anaphylactic shock or immediate reaction, it is not appropriate to choose cephalosporin.
4. People with a history of gastrointestinal disease, especially ulcerative colitis, localized colitis, or antibiotic-associated colitis (cephalosporins rarely produce pseudomembrane colitis) should be used with caution.
5. Due to the low toxicity of cephalosporins, there is no need to adjust the dosage for patients with chronic liver disease. Dosage should be adjusted in patients with severe liver or kidney damage or cirrhosis.
6. In patients with renal insufficiency, no dose adjustment is required when the creatinine clearance is greater than 5m1/ min and the daily dose of this product is less than 2g. Hemodialysis clearance of this product is not large enough to require supplemental dose after dialysis.
7. Interference to diagnosis: patients using this product can obtain false positive reaction when measuring urine sugar by copper sulfate method, but not affected by glucoenzymatic method; Blood urea nitrogen and serum creatinine may be temporarily elevated. Serum biliurin, alkaline phosphatase, alanine aminotransferase (Alt) and aspartate aminotransferase (AST) were all elevated.
8. This product can not be used in hartman's and Ringer's solutions containing calcium.
9. The storage temperature of this product is below 20℃.

4.5 Interaction with other medicinal products and other forms of Interactions

1. Cephalosporins in intravenous infusion with erythromycin, tetracycline, amphotericin B, vasoactive drugs (hydroxyamine, norepinephrine, etc.), phenytoin sodium, chlorpromazine, promazine, vitamin B group, vitamin C, etc., will appear

turbid. Since there are many contraindications of this product, it should be given separately.
2. Disulfirm-like reactions may occur in individual patients when drinking alcohol or taking alcoholic drugs during the use of this product. Therefore, alcohol and alcoholic drugs should be avoided during and for several days after the use of this product.

4.6 Pregnancy and lactation
Although cephalosporins in pregnant and lactating women have not been reported, the advantages and disadvantages of cephalosporins still need to be weighed.

4.7 Child medication
The safety of medication in neonates (birth weight less than 2kg) has not been determined. Newborns with jaundice or severe tendency to jaundice should be used with caution or avoid using this product.

4.8 Elderly medication
Ceftriaxone in the elderly generally does not require dose adjustment unless the elderly patients are weak, malnourished or have severe renal impairment.

4.9 Undesirable effects
The adverse reactions are related to the dosage and course of treatment. Local reactions included phlebitis (1.86%), allergic reactions such as rash, pruritus, fever, bronchospasm and serum sickness (2.77%), headache or dizziness (0.27%), gastrointestinal reactions such as diarrhea, nausea, vomiting, abdominal pain, colitis, jaundice, gas distention, dyspnosia and dyspepsia (3.45%). Laboratory abnormalities accounted for 19%, and hematological abnormalities accounted for 14%, including eosinophilia, thrombocytopenia or thrombocytopenia, and leukopenia. Liver and kidney function were abnormal in 5% and 1.4%.

4.10 Overdose
It's not clear.

4.11 Pharmacology and toxicology
This product is the third generation cephalosporin antibiotics. It has strong activity against enterobacteriaceae bacteria. The mic90 of Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Citrobacter fluraudi, Proteus indole positive, Prudenella and Serratia ranged from 0.12 to 0.25mg/ L. The sensitivity of Enterobacter cloacae, Acinetobacter and Pseudomonas aeruginosa to this product was poor. It has strong antibacterial action against haemophilus influenzae, Neisseria gonorrhoeae and Neisseria meningitidis, and also has good action against hemolytic streptococcus and pneumococcus. The MIC for Staphylococcus aureus was 2-4mg/L. Methicillin-resistant staphylococcus and enterococcus are resistant to this drug. Most bacteroides fragilis are resistant to this drug.

4.12 Pharmacokinetics

After intramuscular injection of 0.5g and 1g, peak plasma concentrations (cmax) of 43mg/l and 80mg/l were reached about 2 hours later. The blood concentration was 6.0mg/ L 24 h after intramuscular injection of 0.5g, and the blood elimination half-life (T1/2) was 7.1 h. The immediate peak concentration (Cmax) of 0.5g was 150.9mg/ L, 24 h later was 9.9mg/ L, and the blood elimination half-life (T1/2) was 7.87 h. Lg was given intravenously within 30 min. The immediate peak concentration (Cmax) at the end of infusion was 150.7mg/ L and the 24-hour peak concentration (Cmax) was 9.3mg/ L. After intramuscular injection of 15-20 mg/kg daily, CSF concentrations averaged 5.16 mg/ L at 6 h and 2.3mg/ L at 12 h in patients with suppurative meningitis. The concentration in bile was 1600mg/ L and 13.5mg/ L at 5 hours and 14 hours after intravenous infusion of 1g of this product. The protein binding rate was 95%. Ceftriaxone is not metabolized in the human body, and about 40% of the drug is excreted in its original form from the biliary tract and intestinal tract, and 60% is excreted in the urine. Benzosulfonate could not increase the plasma concentration or prolong its half-life.

5-Pharmaceutical Particulars :

5.1 Shelf life

36 months

5.2 Special precautions for storage

Shading and airtight storage,and be stored at a temperature not exceeding 25℃.

6-Marketing Authorization Holder :

Anhui Chengshi Pharmaceutical Co.,Ltd.
No.5068.Huaishang Road, Bengbu, Anhui Province, China

7-Name Of Manufacturer :

Anhui Chengshi Pharmaceutical Co.,Ltd.
No.5068.Huaishang Road, Bengbu, Anhui Province, China

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