Summary of Product Characteristics (SmPC)

1. N AME OF THE MEDICINAL PRODUCT

Streptomycin Sulphate for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains: Streptomycin Sulphate

Inactive ingredients: None

3. PHARMACEUTICAL FORM

This product is white or a white-like powder

4. CLINICAL PARTICULARS

【Chemical composition】Streptomycin Sulphate

5. PHARMACOLOGICAL ACTION:

indication

1. This product is mainly used in combination with other anti-tuberculosis drugs for various primary cases of tuberculosis caused by Mycobacterium tuberculosis, or other susceptible mycobacterial infections。2. This product can be used alone for the treatment of tularesis, or in combination with other antimicrobial drugs for the treatment of plague, groinal granuloma, brucellosis, rodent bite fever, etc.

drug interaction

1. The combination with other aminoglycosides or the continuous local or systemic application can increase the possibility of ototoxicity, nephrotoxicity and neuromuscular blockade。 2. The combination with neuromuscular blockade can aggravate the neuromuscular blockade. In combination with cappreomycin, cisplatin, einic acid, furosemide, or vancomycin (or norvancomycin), or continuous local or systemic application may increase ototoxicity and nephrotoxicity。 3. This product is locally or systematically combined with cefothiophene or cefazolin, which may increase nephrotoxicity. 4. Combination with polymyxin injections, or successively continuous local or systemic applications, can increase nephrotoxicity and neuromuscular blockade. 5. Other nephrotoxic drugs and ototoxic drugs should not be used with this product, so as not to aggravate nephrotoxicity or ototoxicity.

pharmacological action

Streptomycin sulfate is an aminoglycoside antibiotic。Streptomycin has a potent antibacterial effect against M. tuberculosis, and its minimum inhibitory

concentration was generally 0.5 g/ml。Nontuberculous mycobacteria are mostly resistant to this product. Streptomycin also has antibacterial effects against many Gram-negative bacteria such as Escherichia coli, Klebsiella, Proteobacteria, Enterobacter, Salmonella, Shigella, Brucella, and Pasteacter； Neisseria meningitidis and N. gonorrhoeae are also susceptible to this product。Streptomycin on Staphylococcus and other Gram-positive cocci. Streptococcus, Pseudomonas aeruginosa and anaerobic bacteria were resistant to this product。Streptomycin binds mainly to the bacterial ribosome 30S subunit and suppresses bacterial protein synthesis. Bacteria are highly susceptible to drug resistance after contact with streptomycin。Combination application of streptomycin and other antimicrobial drugs or anti-tuberculosis drugs can reduce or delay the development of drug resistance.

6.PHARMACOLOGICAL PROPERTIES

usage and dosage

1．Adult dosage (1) intramuscular injection, once 0.5g (0.5 doses) (by streptomycin, the same below), once every 12 hours, combined with other antimicrobial drugs; bacterial (streptococcus) endocarditis, intramuscular injection, 1g (1 dose) every 12 hours, combined with penicillin for 1 week, then 0.5g (0.5 doses) per 12 hours for 1 week; patients over 60 years old should be reduced to 0.5g (0.5 doses per 12 hours) for 2 weeks.

2．Enterococcal endocarditis, intramuscular injection, combined with penicillin, 1g (1 dose) every 12 hours for 2 weeks, followed by 0.5g (0.5 doses) per 12 hours for 4 weeks。(3)Plague, intramuscular injection, once 0.5 to 1 g (0.5 to 1 dose), once every 12 hours, and tetracycline for 10 days。(4)tularasis, intramuscular injection, 0.5 to 1 g (0.5~1 dose) every 12 hours for 7 to 14 days.(5)Tuberculosis, intramuscular injection, 0.5g (0.5 doses) every 12 hours, or 0.75g (dose) once a day, in combination with other anti-tuberculosis drugs; if intermittent therapy, or 2-3 times a week, 1g (1 dose); elderly patient intramuscular injection, once 0.5~0.75g (0.5~ doses) once a day. (6)Brucellosis, 1 to 2 g daily (1 to 2 doses), two intramuscular injections and tetracycline for 3 or more weeks。

3．Commonly used quantity in children , intramuscular injection ，15 to 25 mg / kg per day; for TB, 20mg / kg once a day, maximum daily dose of 1g (1 dose), in combination with other anti-tuberculosis drugs.

4．The normal dose of streptomycin was given once daily with an intramuscular injection of 15mg / kg in patients with normal renal function。Creatinine clearance> 50 to 90 ml/min, 50% of the normal dose every 24 hours; creatinine clearance 10 to 50 ml/min, 50% of the normal dose every 24 to 72 hours; creatinine clearance <10 ml/min, 50% of the normal dose every 72 to 96 hours.

untoward effect

1．Hematuria, decreased urination times or reduced urine volume, loss of appetite, thirst and other nephrotoxicity symptoms, a few can produce blood urea nitrogen and creatinine value increased. 2．When affecting the vestibular function, there may be walking instability, dizziness and other symptoms; affecting the hearing loss, tinnitus and ear fullness. 3．Some patients may appear facial or limb numbness, acupuncture sensation and other peripheral neuritis symptoms.4．Occasionally, vision loss (optic neuritis), drowsiness, weakness, dyspnea and other neuromuscular block symptoms may occur。5．Occasionally, a rash, itching, and redness may appear. A few patients can still have hearing loss, tinnitus, ear fullness and other otoxic symptoms after stopping withdrawal, which should be paid attention to.

Taboo

Patients allergic to streptomycin or other aminoglycosides are prohibited。

matters need attention

1．Patients with crossover allergy to one aminoglycoside may also be allergic to other aminoglycosides。2．Streptomycin should be used with caution in the following situations：(1)Water loss, can make the blood drug concentration increase, easy to produce toxic reaction。(2) Eighth for cranial nerve damage, because this product can cause vestibular nerve and auditory nerve damage。(3)Myasthenia gravis or Parkinson's disease, which can cause neuromuscular blockade, leading to skeletal muscle weakness。(4)Renal function impairment, because this product has nephrotoxicity。3．During the course, the following examinations should be performed regularly: (1) routine urine and renal function measurement to prevent severe nephrotoxic reactions.(2) Hearing examination or audiogram (especially high-frequency hearing) measurement, which is particularly important for elderly patients. 4.If possible, the blood concentration should be monitored and the dose should be adjusted accordingly, especially in newborns, old age and patients with renal dysfunction. The peak concentration should be maintained at 15 to 30 μg/ml for 7.5mg / kg every 12 hours and the trough concentration at 56 to 64 μg/ml and 1 μg/ml for 15mg / kg per day. 5．Interference to diagnosis: This product can increase the measured value of alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum bilirubin concentration and lactate dehydrogenase concentration; the measured value of blood calcium, magnesium, potassium and sodium concentration may be reduced.

Children's precautions：

This product belongs to aminoglycoside, should be used with caution in

pediatrics, especially the kidney tissue of premature infants and newborns is not fully developed, so that the half-life of this kind of drugs is extended, drugs are easy to accumulate in the body and produce toxic reactions。

Notes during pregnancy and lactation：

This product belongs to the class D of pregnant women, which is harmful to human beings, but the advantages may outweigh the disadvantages. This product can cross the placenta into the fetal tissue. It is reported that pregnant women have caused fetal hearing impairment after the application of this product. Therefore, pregnant women must fully weigh the pros and cons before using this product. Breastfeeding women should stop breastfeeding during the medication period。

Care for the elderly：

Elderly patients are prone to various toxic reactions after applying aminoglycosides, and the blood concentration should be monitored as much as possible during the course of treatment. The renal function of elderly patients has a certain degree of physiological decline, even if the measured value of renal function should be used within the normal range。

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7.PHARMACEUTICAL PARTICULARS

7.1 List of excipients

None

7.2Incompatibilities

Not applicable

7.3Shelf-life

3 years

7.4Special precautions for storage

Store in a dry place below 30°C

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

7.5Nature and contents of container

Ampoule

7.6 Special precautions for disposal and other handling

No special requirements

7.7 MARKRTING AUTHORISATION HOLDER

MANUFACTURED BY:

Shandong Xier Kangtai Pharmaceutical Co., Ltd

Private Economy Garden, Xinyan Town, Yanzhou City, Shandong China

IMPORTED BY:

ECNU PHARM CO. LIMITED
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