1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Amoxicillin Sodium for injection 0.5g

2. Qualitative and quantitative composition

Components	Unit dose	Function
Amoxicillin Sodium	Equivalent to amoxicillin 0.5g/vial	Active ingredient

3. Pharmaceutical form

Powder for injection

4. Clinical particulars

4.1 Therapeutic indications

Amoxicillin is indicated in the treatment of infections due to susecptible (ONLY-lactamase-negative) strains of the designated microorganisms in the conditions listed below: Infections of the ear, nose, and throat due to Streptococcus spp. (-and -hemolytic strains only), S. pneumoniae, Staphylococcus spp., or H. influenzae: Infections of the genitourinary tract: Infections of the skin and skin structure, Infections of the lower respiratory tract.

4.2 Posology and method of administration

DOSAGE

I.M.injection or dilutedly I.V. drop. For adults, the recommended dosage is 0.5-1g every 6-8 hours. For children, according to avoirdupois 50- 100mg/KG give mediation, divided into 3-4 times. Patients with impaired hepatic should be adjusted dose. Blood dialysis can eliminate the drug, so give dose after it.

4.3 Contraindications

Amoxicillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (eg. penicillins. cephalosporins).

4.4 Special warnings and precautions for use

Before initiating therapy with amoxicillin. Careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins. Cross-sensitivity between penicillins and cephalosporins is well documented.

Dosage should be adjusted in patients with renal impairment.

Amoxicillin should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin.

Chloramphenicol, macrolides, sulfonamides, and tetracy-clines may interfere with the bactericidal effects of penicillin.

Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

In common with other broad spectrum antibioties, amoxicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

4.6 Pregnancy and lactation

The safety of this medicinal product for use in human pregnancy has not been established by well controlled studies in pregnant women. Reproduction studies have been performed in mice and rats at doses up to ten times the human dose and these studies have revealed no evidence of impaired fertility or harm to the foetus due to amoxicillin.Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Amoxicillin is excreted into breast milk in small quantities with the possible risk of sensitisation. Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the lactation infant, so that lactation might have to be discontinued. Amoxicillin should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 Undesirable effects

There are report occasionally that occurs side effects including nausea, diarrhea, abdominal pain, malaise, headacheand swirl and so on, however, the normal treatment can continue going.

4.9 Overdose

Symptoms and signs

Gastrointestinal symptoms (such as nausea, vomiting and diarrhoea) and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. A regular check of patency should be maintained。

Management

Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance.

Amoxicillin can be removed from the circulation by haemodialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Amoxicillin is a semi-synthetic aminopenicillin of the beta-lactam group of antibiotics which exerts a bactericidal effect against many Gram-positive and Gram-negative microorganisms by inhibiting cell-wall synthesis to make bacterial dissolving and bursting. Amoxicillin is not effective against beta-lactamase producing organisms.

5.2 Pharmacokinetic properties

A peak plasma concentration is observed at 1 hour after 0.5g dose of intramuscular injection, average peak concentration is 14 mg/L, while after 0.5g dose of mainline, plasma concentration is 42.6mg/L and 1mg/Lat 5 minutes and 5 hours, respectively. Amoxicillin diffuses readily into most body tissues and fluids. 17%-20% of the dose of Amoxicillin is bound to plasma proteins. The elimination half-life is 1.08 hours. 60%- 70% of amoxicillin is excreted unchanged in urine, approximately 24% metabolized in hepatic.

5.3 Preclinical safety data

No further information of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Not applicable

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25℃.

6.5 Nature and contents of container

Moulded vial made of soda lime glass

6.6 Special precautions for disposal and other handling

Use as directed by a physician.

7. Manufacturer

CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

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