Summary of Product Characteristics(SmPC)

1. Name of the finished pharmaceutical product

Amoxicillin capsules 500mg

2. Qualitative and quantitative composition

500mg

Each capsules: Amoxicillin trihydrate equivalent to 500mg anhydrous amoxicillin

3. Pharmaceutical form

Oral capsules

Yellow capsule cap with brown capsule body, inside with white powder

4. Clinical particulars

4.1 Therapeutic indications

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Amoxicillin and other antibacterial drugs, AMOXICILLIN should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

AMOXICILLIN is indicated in the treatment of infections due to

susceptible (ONLY β-lactamase–negative) isolates of the designated bacteria in the conditions listed below:

Infections of the ear, nose, and throat due to Streptococcus species (α- and β-hemolytic isolates only), Streptococcus pneumoniae, Staphylococcus spp., or Haemophilus influenzae;

Infections of the genitourinary tract due to Escherichia coli, Proteus mirabilis, or Enterococcus faecalis;

Infections of the skin and skin structure due to Streptococcus spp. (α- and β-hemolytic isolates only), Staphylococcus spp., or E. coli;

Infections of the lower respiratory tract due to Streptococcus spp. (α- and β-hemolytic isolates only), S. pneumoniae, Staphylococcus spp., or H. influenzae;

Gonorrhea, acute uncomplicated (ano-genital and urethral infections in males and females) due to Neisseria gonorrhoeae

Because of high rates of amoxicillin resistance, AMOXICILLIN is not recommended for empiric treatment of gonorrhea. AMOXICILLIN use should be limited to situations where N. gonorrhoeae isolates are known to be susceptible to amoxicillin.

Triple therapy for Helicobacter pylori with clarithromycin and lansoprazole.

AMOXICILLIN, in combination with clarithromycin plus lansoprazole as

triple therapy, is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

Dual therapy for H. pylori with lansoprazole

AMOXICILLIN, in combination with lansoprazole delayed-release capsules as dual therapy, is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected. (See the clarithromycin package insert, Microbiology.) Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

4.2 Posology and method of administration

Amoxicillin is the 4-hydroxy analogue of ampicillin and is used similarly in susceptible infections. These include actinomycosis, anthrax, biliary-tract infections, bronchitis, endocarditis (particularly for prophylaxis), gastro-enteritis (including salmonella enteritis, but not shigellosis), gonorrhoea, Lyme disease, mouth infections, otitis media, pneumonia, spleen disorders (pneumococcal infection prophylaxis), typhoid and paratyphoid fever, and urinary-tract infections. The beta-lactamase inhibitor clavulanic acid widens amoxicillin's antimicrobial spectrum and

a combined preparation (co-amoxiclav) can be used when resistance to amoxicillin is prevalent, for example in respiratory-tract infections due to Haemophilus influenzae or Moraxella catarrhalis (Branhamella catarrhalis), in the empirical treatment of animal bites, or in melioidosis. For details of these infections and their treatment, see under Choice of Antibacterial.

Amoxicillin is also given as part of treatment regimens to eradicate Helicobacter pylori infection in patients with peptic ulcer disease.

Administration and dosage. Amoxicillin is given by mouth as the trihydrate and by injection as the sodium salt. Doses are expressed in terms of the equivalent amount of amoxicillin; 1.06 g of amoxicillin sodium and 1.15 g of amoxicillin trihydrate are each equivalent to about 1 g of amoxicillin.

The usual oral dose is 250 to 500 mg every 8 hours, or 500 to 875 mg every 12 hours. Children up to 10 years of age may be given 125 to 250 mg every 8 hours; for those under 40 kg, a dose of 20 to 40 mg/kg daily in divided doses every 8 hours, or 25 to 45 mg/kg daily in divided doses every 12 hours, may be used; in infants less than 3 months old, the maximum dose should be 30 mg/kg daily in divided doses every 12 hours.

Higher oral doses of amoxicillin, either as a single dose or in short courses, are used in some conditions. For example, a dose of 3 g repeated once after 8 hours may be used for dental abscesses. A 3-g dose may be given for

uncomplicated acute urinary-tract infections, and repeated once after 10 to 12 hours.

Amoxicillin is used in the treatment of a variety of a variety of infections due to susceptible organisms, including respiratory tract infections, urinary tract infections, gonorrhoea, enteric infections, meningitis and septicaemia. The dosage of amoxicillin will depend on the severity of the disease, the age of the patient and then renal function.

4.3 Contraindications

Hypersensitivity to penicillin.

4.4 Special warnings and precautions for use

Amoxicillin should preferably not be given to patients with mononuleosis since they are susceptible to Amoxicillin induced skin rashed.

4.5 Interaction with other medicinal products and other forms of interaction

Amoxicillin may decrease efficacy of oestrogen containing oral contraceptives and it may also affect the absorption of other drugs due to its effect on the gastrointestinal flora.

4.6 Pregnancy and lactation

The disposition is altered in pregnancy resulting in less than adequate antibacterial concentration. Amoxicillin is excreted in very small amounts in breast milk, the amount likely to be well below the normal pediatric dose.

4.7 Effects on ability to drive and use machines

Amoxicillin is resistant to inactivation by gastric acid. It is more rapidly and more completely absorbed than ampicillin when given by mouth. Peak plasma-amoxicillin concentrations of about 5 micrograms/mL have been observed 1 to 2 hours after a dose of 250 mg, with detectable amounts present for up to 8 hours. Doubling the dose can double the concentration. The presence of food in the stomach does not appear to diminish the total amount absorbed.

Concentrations of amoxicillin after intramuscular injection are similar to those achieved with oral doses.

4.8 Undesirable effects

4.9 Overdose

There is no specific antidote for amoxicillin. Treatment is primarily symptomatic and supportive. Decrease absorption (induction of emesis or gastric lavage, multiple doses of charcoal), enhance elimination (dialysis is indicated to aid the removal of penicillins from the blood), monitor and give supportive care.

5. Pharmacological properties

5.1 Pharmacokinetic properties

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plasma-amoxicillin concentrations of about 5 micrograms/mL have been observed 1 to 2 hours after a dose of 250 mg, with detectable amounts present for up to 8 hours. Doubling the dose can double the concentration. The presence of food in the stomach does not appear to diminish the total amount absorbed.

Concentrations of amoxicillin after intramuscular injection are similar to those achieved with oral doses.

About 20% is bound to plasma proteins and plasma half-lives of 1 to 1.5 hours have been reported. The half-life may be prolonged in neonates, the elderly, and patients with renal impairment; in severe renal impairment the half-life may be 7 to 20 hours. Amoxicillin is widely distributed at varying

5.2 Preclinical safety data

Because of incompletely developed renal function in neonates and young infants, the elimination of amoxicillin may be delayed. Dosing of AMOXICILLIN should be modified in pediatric patients 12 weeks or younger (≤3 months). (See DOSAGE AND ADMINISTRATION: Neonates and Infants.)

6. Phamaceutical particulars

6.1List of excipients

Microcrystalline cellulose

Sodium starch glycolate

Magnesium stearate

6.2 Incompatibilities

No incompatibilities are known to date

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30℃. Store in the original package.

6.5 Nature and contents of container

PVC and Aluminum foil

10 capsules/blister, 10blisters/box

6.6 Special precautions for disposal and other handling

None

7.Marketing authorization holder

Shandong Xier Kangtai Pharmaceutical Co.,Ltd.

Private economy Garden, Xinyan Town, Yanzhou District, Jining City

8.Marketing authorization number(s)

LU20160143

9.Date of first authorization of the authorization

06/05/2010

10.Date of revision of the text

05/2018