Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Amoxycillin Sachet Sugar Free 125mg Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of product contains 125 mg of amoxicillin as amoxicillin trihydrate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension
A lemon coloured, dry, free flowing powder with a characteristic lemon flavour for reconstitution in water.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Amoxycillin is a broad spectrum antibiotic indicated for the treatment of commonly occurring bacteria infections such as:

Upper respiratory infections, otitis media, acute and chronic bronchitis, lobar and bronchopneumonia, cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy, gynaecological infections including puerperal sepsis and septic abortion, gonorrhoea, peritonitit, intra - abdominal sepsis, septiceamia, bacterial endocarditis, typhoid and parathphoid fever, skin and soft tissue infections, osteomyelitis.
Amoxycillin may be used for the prevention of bacteraemia associated with procedures such as dental extraction in patients as risk of developing bacterial endocarditis.

4.2 Posology and method of administration

Dosage: The absorption of Amoxycillin is virtually unimpaired by the presence of food.

Standard Adult Dose: 250mg three times daily by the oral route.
In cases of severe infection the dosage may be doubled.

Children: (Up to 10 years).
125mg three times daily by the oral route.

4.3 Contraindications

Use in patients with hypersensitivity to traditional and semi-synthetic penicillins or cephalosporins.

4.4 Special warnings and precautions for use

As with other penicillins, side effects are rare and usually of a mild and transitory nature. Gastrointestinal side effects, such as nausea, vomiting and diarrhoea are sometimes observed.

Macular or maculopapular rashes and urticaria may occur.

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

In patients with infectious mononucleosis an increased incidence of rashes can occur with amoxycillin therapy.

Each sachet contains 1 gram of sorbitol. If you are taking the standard adult daily dose of 750 mg of amoxicillin you will also be taking 6g of sorbitol each day. In cases of severe infection the dosage may be doubled, it is then possible that you could be taking up to 12g of sorbitol each day. Sorbitol may have a mild laxative effect. Calorific value 2.6 kcal/g sorbitol.

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy.

Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in persons with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with a cephalosporin. Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens.

If an allergic reaction occurs, amoxycillin should be discontinued and appropriate therapy should be instituted and discontinuance of amoxycillin therapy considered.

Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concurrently, the following drugs may interact with amoxycillin:

Bacteriostatic antibiotics
Chloramphenicol, erythromycins, sulfonamides, or tetracyclines may interfere with the bactericidal effects of penicillins. This has been demonstrated in vitro; however, the clinical significance of this interaction is not well documented.

Probencid
Probencid may decrease renal tubular secretion of amoxycillin resulting in increased blood levels and/or amoxycillin toxicity.

Drug/Laboratory Test Interactions
After treatment with amoxycillin, false - positive reaction for glucose in the urine may occur with copper sulphate tests (Benedict’s solution, Fehling’s solution, Clinitest tablets) but not with enzyme based tests such as Clinistix and Tes-Tap.

4.6 Pregnancy and lactation

As there is insufficient experience with pregnant women the product should not be used during pregnancy unless considered essential by the physician.

As for other penicillins, during lactation, trace quantities of amoxycillin can be detected in breast milk, presenting the risk of candidiasis and also of a CNS toxicity due to prematurity of the blood brain barrier. There is a theoretical possibility of later sensitisation in the baby if penicillins are used during the second and third trimesters of pregnancy.

4.7 Effects on ability to drive and use machines

No known adverse effects are reported.

4.8 Undesirable effects

Side - effects, as with other penicillins are uncommon and mainly of a mild and transitory nature; they may include nausea, vomiting, diarrhoea, indigestion or occasionally a rash, either urticarial or erthyematous. An urticular rash suggests penicillin - hypersensitivity and the erthematous type rash may arise if amoxycillin is administered to patients with glandular fever. In either case, treatment should be discounted. Antibiotic associated colitis has also been reported.

A sore mouth or black hairy tongue have been reported occasionally. Hypersensitivity reactions including fever, joint pains, angioedema, anaphylaxis, serum sickness-like reactions, haemolytic anaemia and interstitial nephritis have been documented. Neutropenia, thrombocytopenia, coagulation disorders and central nervous system disorders have been reported especially with high doses or in severe renal impairment.
A temporary increase in liver enzymes may occur occasionally.

4.9 Overdose

Since amoxycillin is a penicillin, problems of overdosage are unlikely to be encountered.
In case of overdosage, discontinue medication, treat symtomatically and institute supportive measures as required.
Amoxycillin can be removed from the circulation by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxycillin is a broad spectrum antibiotic which is bactericidal for both gram positive and gram negative bacteria. In common with other penicillins Amoxycillin is bactericidal by virtue of inhibition of bacterial cell wall synthesis. Amoxycillin gives good penetration into bronchial secretions and high urinary concentrations of unchanged antibiotic. It is rapidly bactericidal and possesses the safety profile of a penicillin.

5.2 Pharmacokinetic properties

Amoxycillin trihydrate is a semisynthetic antibiotic, an analog of ampicillin, with a broad spectrum of bactericidal activity against many gram - positive and gram - negative micro – organisms.

Amoxycillin is stable in the presence of gastric acid and may be given without regard to meals. It is rapidly absorbed after oral administration. 50% to 90% of a dose is absorbed after oral administration. It diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. The serum half life of amoxycillin is 1 hour, which may be increased to 20 hours in the case of renal failure. Most of the amoxycillin is excreted unchanged in the urine. Amoxycillin is not highly protein bound. In blood serum, amoxycillin is approximately 15% to 20% protein bound as compared to 60% for penicillin G.

Detectable serum levels are observed up to 8 hours after an orally administered dose of amoxycillin. Approximately 60% of an orally administered dose of amoxycillin is excreted in the urine within six to eight hours.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Sodium citrate
Lemon flavour
Quinoline yellow
Xanthum gum
Sorbitol

6.2 Incompatibilities

None known.

6.3 Shelf Life

The shelf life expiry date for this product should not exceed 6 months from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 25^{o}C. Keep the sachets in the outer carton.

6.5 Nature and contents of container

The powder is presented in individual sachets with dimensions of approximately 90 x 45 mm and composed of a paper/polyethylene/aluminium foil/polyethylene laminate.

The sachets are packaged in outer cardboard cartons of 25 or 50.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

To prepare add 80 mls of potable water and stir the contents until all are dispersed.
For single use only. Discard any unused medicine, immediately.

7 MARKETING AUTHORISATION HOLDER

Athlone Laboratories Ltd.
Ballymurray
Co. Roscommon
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 298/10/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 October 1993

Date of last renewal: 21 October 2003

10 DATE OF REVISION OF THE TEXT

October 2004