Summary of Product Characteristics

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Name of the Medicinal Product

Amoxicillin Oral Suspension BP 125mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml after reconstitution contains:

Amoxicillin Trihydrate BP

Eq. to Amoxicillin 125mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for Suspension

Off-white coloured granular powder forming light orange coloured suspension after reconstitution with water.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

The treatment of bacterial infections caused by Amoxicillin-susceptible organisms.

It is principally indicated for respiratory, middle ear and urinary tract, Biliary and intra-abdominal, Gynaecological, Gonorrhoea, Septicaemia, Bacterial endocarditis, Skin and soft tissue infections, Meningitis, Enteric fevers, Dental abscess.

The prevention of bacteraemia, associated with procedures, in patients at risk of developing bacterial endocarditis.

4.2 Posology and Method of administration

Method of administration: Oral

Dosage:

Note: One teaspoon is equivalent to 5 ml

Adults and childrens with a mass more than 40kg:

250mg to 500mg three times per day. The latter dosage is for the more severe infections.

Age and Mass	**% of Adult Dose**	**Usual total daily dose range***
Adults (65kg)	100%	750mg – 1,5g
12 years (40kg)	75%	525mg – 1,125mg
7 years (23kg)	50%	375 mg – 750mg
1 years (10kg)	25%	187mg – 375 mg
*Administered in divided doses three times per day		

Fir in between ages, in between percentages are used, e.g at 10 years 66% and at three years 33% of the adult dose. The above percentage methods of calculating dosage is based on the formula.

Surface are of child x 100 = percentage of adult dose

Surface area of adult

Infants:-

The recommended dosage is 20 mg/kg/day in three equally divided doses.

Direction of Mixing: Add freshly boiled, cooled water up to the mark on the bottle and shake vigorously. Adjust the volume up to the mark buy adding more water if necessary. This makes a 100ml suspension. The prepared suspension should be used one week after preparation and should be stored in a cool place. Protect from light.

4.3 Contraindications

Amoxicillin is contra-indicated in patients with hypersensitivity to penicillins.

Attention should also be paid to possible cross-reactivity with other beta-lactam antibiotics e.g. cephalosporins.

It should not be given to patients with infectious mononucleosis (glandular fever) since they are especially susceptible to amoxicillin-induced skin rashes.

4.4 Special warnings and precautions for use

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are most likely in those with a history of hypersensitivity to beta-lactam antibiotics.

Amoxicillin should be used with caution in those with impaired renal function and dose reduction may be necessary in severe impairment.

Patients with infectious mononucleosis (glandular fever), lymphatic leukaemia and possibly with HIV infection are particularly prone to developing erythematous rashes with amoxicillin. Amoxicillin should be discontinued if a skin rash occurs.

Prolonged use of an anti-infective may result in the overgrowth of non-susceptible organisms (superinfection).

4.5 Interaction with other medicinal products and other forms of interact.

Prolongation of prothrombin time has been reported in patients taking amoxicillin. In common with other broad spectrum antibiotics Amoxicillin may reduce the efficacy of the oral contraceptive pill.

Excretion of penicillins is reduced by probenecid

4.6 Fertility, Pregnancy and Lactation

There is no evidence that amoxicillin is teratogenic or fetotoxic in humans. The product has been in extensive clinical use form any years and is considered safe in pregnancy.

Amoxicillin is considered safe in lactation. However it should be noted that amoxicillin is excreted in breast milk in small quantities with the possible risk of sensitization and subsequent allergic reactions in a sensitized infant

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

When Amoxicillin is administered to a hypersensitive patient anaphylactic shock with collapse and sometimes death may occur within minutes.

Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous and exfoliative dermatitis have been reported.

Severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness and vasculitis reported rarely.

Nausea, vomiting diarrhoea. Muco-cutaneous candidiasis. Antibiotic-associated colitis, raised liver enzymes (AST and/or ALT), dizziness, convulsions and paraesthesia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Overdosages with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

In the event of accidental overdose, treatment consists of supportive measures. Within the first hour after ingestion gastric lavage may be performed. Activated charcoal may be given if considered appropriate.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Amoxicillin is bactericidal. Like all penicillins it acts by interfering with the synthesis of the cell wall of the bacterium.

Amoxicillin is inactivated by penicillinase. Penicillinase-producing strains of Staphylococcus aureus and Gram negative organisms (e.g. Escherichia coli, Proteus, Klebsiella) are resistant.

Complete cross-resistance occurs with ampicillin and Amoxicillin.

5.2 Pharmacokinetic properties

Amoxicillin is stable in the acid gastric secretion and is rapidly absorbed from the gastrointestinal tract after oral administration. The presence of food does not interfere with this process. Peak plasma

concentrations are obtained in about two hours, producing around 2.5 times the peak concentration resulting from comparable doses of ampicillin. Protein binding is similar to that of ampicillin: up to 25%. About 60% of an orally administered dose is excreted unchanged in the urine. It penetrates well in to purulent and mucoid sputum.

5.3 Preclinical safety data

None stated.

6.0 Pharmaceutical particulars

6.1 List of excipients

Colloidal Anhydrous Silica, Carmellose Sodium, Sodium Benzoate, Orange Flavour (Dry), Colour Sunset Yellow Supra, Disodium Edetate, Sodium Citrate, Sucrose.

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light. Keep out of reach of children. Use the reconstituted oral suspension within 7 days of preparation.

6.5 Nature and contents of container

100 ml HDPE bottle with ROPP cap

6.6 Special precautions for disposal and other handling

Shake well before use.

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 07660/08393/REN/2022

9. Date of first authorisation/renewal of the authorisation

Aug 8, 2022

10. Date of revision of the text

August 2023