SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product

Moxacil powder for oral suspension.

2. Qualitative and quantitative composition

Each 5mL contains: Amoxicillin (as Trihydrate) 125mg after reconstitution.

For more information on excipients see section 6.1

3.0 Pharmaceutical form: Powder for oral suspension.

A whitish coloured, free flowing granular powder yields a yellow coloured suspension on reconstitution, with an orange flavour.

4.0 Clinical particulars

4.1 Therapeutic indications

Treatment of Infections: Amoxicillin is a broad spectrum antibiotic indicated for the treatment of commonly occurring bacterial infections such as: Upper respiratory tract infections, Otitis media, Acute and chronic bronchitis, Chronic bronchial sepsis, Lobar and bronchopneumonia, Cystitis, urethritis, pyelonephritis, Bacteriuria in pregnancy, Gynaecological infections including puerperal sepsis and septic abortion, Gonorrhoea, Peritonitis, Intra-abdominal sepsis, Septicaemia, Bacterial endocarditis, Typhoid and paratyphoid fever, Skin and soft tissue infections, Dental abscess (as an adjunct to surgical management).

In children with urinary tract infection the need for investigation should be considered.

Prophylaxis of endocarditis: Amoxicillin may be used for the prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis.

4.2 Posology and method of administration:

Method of administration: For oral administration.

Adult dosage (including elderly patients):

Standard adult dosage: 250 mg three times daily, increasing to 500 mg three times daily for more severe infections.

High dosage therapy (maximum recommended oral dosage 6 g daily in divided doses): A dosage of 3 g twice daily is recommended in appropriate cases for the treatment of severe or recurrent purulent infection of the respiratory tract.

Short course therapy: Simple acute urinary tract infection: two 3 g doses with 10-12 hours between the doses. Dental abscess: two 3 g doses with 8 hours between the doses. Gonorrhoea: single 3 g dose.

Children dosage (up to 10 years of age)

The standard children dosage: 125mg 3 times daily, increasing to 250mg 3 times daily for more severe infections

Moxacil suspension is recommended for children under 6 months of age.

In severe or recurrent acute otitis media, especially where compliance may be a problem, 750 mg twice daily for 2 days may be used as an alternative course of treatment in children aged 3 to 10 years

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). Precaution should be taken in premature children and during the neonatal period: renal, hepatic and haematological functions should be monitored.

4.5 Interaction with other medicinal products and other forms of interaction

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

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

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

4.6. Pregnancy and lactation

Use in pregnancy: Animal studies with Amoxicillin have shown no teratogenic effects. The product has been in extensive clinical use and its suitability in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Amoxicillin may be considered appropriate when the potential benefits outweigh the potential risks associated with treatment.

Use in lactation: Amoxicillin may be given during lactation. With the exception of the risk of sensitization associated with the excretion of trace quantities of amoxicillin in breast milk, there are no known detrimental effects for the breast-fed infant.

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

Skin rashes are among the most common adverse effects and are generally either urticarial or maculopapular. Gastrointestinal adverse effects, particularly diarrhea, nausea and vomiting occur quite frequently on oral use. Pseudomembranous colitis has also been reported.

4.9 Overdose and treatment

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Amoxicillin may be removed from the circulation by haemodialysis.

5. 0 Pharmacological properties

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: *Penicillins with extended spectrum**; ATC code:** J01CA04.*

Pharmacology: Amoxicillin has been reported to be more active *in vitro* than ampicillin against *Enterococcus faecalis, Helicobacter pylori*, and *Salmonella* spp., but less active against *Shigella* spp.

Amoxicillin is inactivated by beta lactamases and complete cross-resistance has been reported between amoxicillin and ampicillin. The spectrum of activity of amoxicillin may be extended by use with a beta-lactamase inhibitor such as clavulanic acid. As well as reversing resistance to amoxicillin in beta-lactamase-producing strains of species otherwise sensitive, clavulanic acid has also been reported to enhance the activity of amoxicillin against several species not generally considered sensitive. These have included *Bacteroides, Legionella*, and *Nocardia* spp., *Haemophilus influenzae, Moraxella catarrhalis* (*Branhamella catarrhalis*), and *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*). However, *Ps. aeruginosa, Serratia marcescens,* and many other Gram-negative bacteria remain resistant. Transferable resistance has been reported in *H. pylori*.

Pharmacodynamic: Amoxicillin binds to penicillin-binding protein located inside the bacterial cell well. Penicillins acylate the penicillin-sensitive transpeptidase C-terminal domain by opening the lactam ring. This inactivation of the enzyme prevents the formation of a cross-link of two linear peptidoglycan strands, inhibiting the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins.

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%.

Effective levels in the cerebrospinal fluid are obtained only in the presence of inflammation and then irregularly. 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

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Orange flavour,
Sodium benzoate,
Sodium citrate,
Disodium edetate,
Egg yellow colour,
Sucrose,
Aerosil
Xanthan gum.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months from the date of manufacture. (3 years).
Use the reconstituted suspension within 7days.

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from direct sunlight.

6.5 Nature and contents of container

Packed in100ml and 60ml HDPE bottles in a unit box along with a literature insert.

6.6 Special precautions for disposal and other handling

None applicable.

7.0 Marketing authorization holder/Registrant.

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8.0 Manufacturer

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