Important Information. Please read carefully.

Moxipen®

Capsule / Powder For Oral Suspension

Composition

Moxipen Capsule

Each capsule contains Amoxycillin Trihydrate equivalent to Amoxycillin Anhydrous 250 mg.

Moxipen Oral Suspension

Each 5 mL reconstituted suspension contains Amoxycillin Trihydrate equivalent to Amoxycillin Anhydrous 125 mg. Sodium Benzoate 0.1% w/v as preservative.

Pharmacodynamics

Amoxycillin is a beta-lactam antibiotic and has a bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria and *Corynebacterium xerose*. It exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis. Amoxicillin is inactivated by beta lactamases and complete cross-resistance has been reported between amoxicillin and ampicillin. 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. and *Haemophilus influenzae*.

Pharmacokinetics

Amoxycillin is resistant to inactivation by gastric acid. It is more rapidly and more completely absorbed than ampicillin when given orally. The presence of food in the stomach does not appear to diminish the total amount absorbed. About 20% is bound to plasma proteins and plasma half-lives of 1 to 1.5 hours have been reported. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. It crosses the placenta; small amounts are distributed into breast milk. About 60% of an oral dose of amoxicillin is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion. High concentrations have been reported in bile; some may be excreted in the faeces.

Indications

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

Upper respiratory tract infections e.g. ear, nose and throat infections, otitis media.

Lower respiratory tract infections e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia.

Gastrointestinal tract infections e.g. typhoid and paratyphoid fever.

Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy, septic abortion, puerperal sepsis.

Skin and soft tissue infections.

Biliary tract infections.

Bone infections.

Pelvic infections.

Gonorrhoea (non-penicillinase producing strains).

Septicaemia.

Endocarditis.

Meningitis.

Peritonitis.

Dental abscess (as an adjunct to surgical management).

Helicobacter pylori eradication in peptic (duodenal and gastric) ulcer disease.

Infections such as septicaemia, endocarditis and meningitis due to susceptible organisms should be treated initially with high doses of a parenteral therapy and, where appropriate, in combination with another antibiotic.

Prophylaxis of endocarditis: **Moxipen** may be used for the prevention of bacteraemia associated with procedures such as dental extraction, in patients at risk of developing endocarditis (see Table in *Dosage and Administration*).

Dosage and Administration

Moxipen is stable in the presence of gastric acid and may be given before or after food.

Adults:

- *Standard adult dosage:* 250 mg every 8 hours, increasing to 500 mg every 8 hours 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 to 12 hours between the doses.
  Dental abscess: two 3 g doses with 8 hours between the doses.
  Gonorrhoea: single 3 g dose.
- *Helicobacter eradication in peptic (duodenal and gastric) ulcer disease:*
  Moxipen is recommended at a dose of twice daily in association with a proton pump inhibitor and antimicrobial agents as detailed below:
  Omeprazole 40 mg daily, Amoxicillin 1 g twice a day, Clarithromycin 500 mg twice a day for 7 days.
  or Omeprazole 40 mg daily, Amoxicillin 750 mg to 1 g twice a day, Metronidazole 400 mg 3 times a day for 7 days.

Children

Moxipen Powder for Oral Suspension is recommended for children under 6 months of age.

Infants/ Children	*8 hourly*
Up to 6kg	25mg – 50 mg
6 – 8 kg	50mg – 100mg
8 – 20 kg	6.7mg – 13.3mg per kg body weight
Above 20kg	250mg – 500mg

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

Patients with renal impairment:

In renal impairment, the excretion of the antibiotic will be delayed and, depending on the degree of impairment, it may be necessary to reduce the total daily dosage according to the following scheme:

Adults and Children over 40 kg:	
Mild impairment (creatinine clearance greater than 30 mL/min)	No change in dosage
Moderate impairment (creatinine clearance 10 to 30 mL/min)	500 mg twice a day maximum
Severe impairment (creatinine clearance less than 10 mL/min)	500 mg/day maximum

Children under 40 kg:	
Mild impairment (creatinine clearance greater than 30 mL/min)	No change in dosage
Moderate impairment (creatinine clearance 10 to 30 mL/min)	15 mg/kg twice a day (maximum 500 mg/ twice daily)
Severe impairment (creatinine clearance less than 10 mL/min)	15 mg/kg once a day (maximum 500 mg)

Patients receiving peritoneal dialysis:
Dosing as for patients with severe renal impairment (creatinine clearance less than 10 mL/min). Amoxicillin is not removed by peritoneal dialysis.

Patients receiving haemodialysis:
Dosing as for patients with severe renal impairment (creatinine clearance less than 10 mL/min). Amoxicillin is removed from the circulation by haemodialysis. Therefore, 1 additional dose (500 mg for adults or 15 mg/kg for children under 40 kg) may be administered during dialysis *and* at the end of each dialysis.

Prophylaxis of endocarditis:	
Conditions	Dental procedures: In patients with the highest risk of infective endocarditis that require manipulation of the gingival or periapical region of the teeth, or perforation of the oral mucosa.
	Patients not having general anaesthetic.
Adults and children over 40kg	2 g as a single oral dose 30 to 60 minutes before procedure
Children under 40kg	50 mg/kg as a single oral dose 30 to 60 minutes before procedure.

Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.

In renal impairment the excretion of the antibiotic will be delayed and depending on the degree of impairment, it may be necessary to reduce the total daily dosage.

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

Contraindications
Moxipen is contraindicated in patients allergic to penicillins and in patients with infectious mononucleosis.

Precautions
Patients with impaired renal function may require smaller doses. Avoid prolonged use as this may lead to overgrowth of non-susceptible organisms.

As with any other potent drug, monitoring of renal, hepatic and hematopoietic functions should be carried out during prolonged therapy. Serious and occasionally fatal hypersensitivity (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, **Moxipen** must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management (including intubation) may also be required.

The safety of **Moxipen** for use during pregnancy has not been established.

Incompatibility and Drug Interactions
None known.

Side Effects
As with other penicillins, the following adverse reactions may occur:

Hypersensitivity Reactions: Erythematous maculopapular rashes and urticaria which can be controlled with antihistamine and if necessary, systemic corticosteroids. If the hypersensitivity reactions occur, treatment should be discontinued.

Gastrointestinal: Nausea, vomiting and diarrhoea.

Liver: A moderate increase in serum concentration of AST (SGOT) has been noted, but the significance of this finding is unknown.

Blood Dyscrasia: Eosinophilis, haemolytic anaemia, anaemia, leukopenia, neutropenia, agranulocytosis, thrombocytopenia, thrombocytopenia purpura and acute interstitial have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Skin and Subcutaneous Tissue Disorders:
Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Nervous System Disorders:
Frequency 'very rare': Aseptic meningitis.

Symptoms and Treatment of Overdosage
Moxipen is virtually non-toxic to man. Excessive doses may have irritative effects on the gastrointestinal tract, causing nausea with or without vomiting and mild to severe diarrhoea. There is no specific antidote. Symptomatic treatment should be given.

Shelf-life
Moxipen Capsule**:** The expiry date is indicated on the packaging.
Moxipen Oral Suspension: The expiry date is indicated on the packaging.

Presentation
Moxipen Capsule: Maroon and yellow capsules with 'XSP' printed. Available in packs of 1000's.
Moxipen Oral Suspension: Ready-to-dispense bottle containing white powder for preparing yellow, fruity-flavoured suspension in packs of 60 mL.

Storage
Moxipen Capsule: Store below 30ºC.
Moxipen Oral Suspension:
Before and after reconstitution: Store in a cool, dry place below 25ºC

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK
For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder
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