MEGAMOX®JPI

(Amoxycillin and clavulanic acid)

PROPERTIES

Megamox-JPI is an oral antibacterial combination consisting of the semisynthetic broad spectrum antibiotic Amoxycillin and the β-lactamase enzymes inhibitor Clavulanic acid, which protects Amoxycillin from destruction and subsequent loss of antibacterial activity by the β-lactamase enzymes produced by many Gram-negative and Gram-positive bacteria. This combination effectively extends the antibacterial spectrum of Amoxycillin to embrace many bacteria normally resistant by virtue of their ability to produce β-lactamase. Amoxycillin and Clavulanic acid are well absorbed from the gastrointestinal tract after oral administration of Megamox-JPI. Megamox-JPI is bactericidal to a wide range of β-lactamase and non β-lactamase producing Gram-positive and Gram-negative bacteria including :

Aerobic Gram-positive: Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus viridans, Bacillus anthracis, Corynebacterium sp., and Listeria monocytogenes.

Anaerobic Gram-positive: Clostridium sp., Peptococcus sp., and Peptostreptococcus sp.

Aerobic Gram-negative: Moraxella (Branhamella) catarrhalis, Haemophilus influenzae, Haemophilus ducreyi, Escherichia coli, Proteus mirabilis, Proteus vulgaris, Salmonella sp., Shigella sp., Klebsiella sp., Bordetella pertussis, Yersinia enterocolitica, Brucella sp., Neisseria meningitidis, Neisseria gonorrhoea, Pasteurella multocida, Campylobacter jejuni, and Vibrio cholerae.

Anaerobic Gram-negative: Bacteroides sp. including Bacteroides fragilis.

INDICATIONS

Megamox-JPI is indicated for the treatment of infections caused by susceptible organisms involving the respiratory tract, skin and skin structure, and urinary tract infections.

DOSAGE AND ADMINISTRATION

Adults :

- In mild to moderate infections: one Megamox-JPI 625 mg tablet twice daily or one Megamox-JPI 375 mg tablet three times daily.
- In lower respiratory tract infections and more severe infections: one Megamox-JPI 1 g tablet twice daily or one Megamox-JPI 625 mg tablet three times daily.

Children :

Based on the Amoxycillin component, Megamox-JPI should be dosed as follows :

- Neonates and infants aged less than 12 weeks (3 months): 30 mg/kg/day divided into 2 doses (q 12 h) or 20 mg/kg/day divided into 3 doses. In more serious infections the dosage may be increased up to 40 mg/kg/day divided into 3 doses.
- Patients aged 12 weeks (3 months) and older: as shown in the table below

Infections	Dosing regimen			
	Twice daily (q 12 h)		Three times daily (q 8 h)	
	Oral suspension		Oral suspension	
	Megamox-JPI 228 mg	Megamox-JPI 457 mg	Megamox-JPI 156 mg	Megamox-JPI 312 mg
Otitis media, sinusitis, lower respiratory tract infections and more severe infections	0.56ml/Kg (22.5 mg/Kg)	0.28ml/Kg (22.5 mg/Kg)	0.53ml/Kg (13.3 mg/Kg)	0.27ml/Kg (13.3 mg/Kg)
Less severe infections	0.31 ml/Kg (12.5 mg/kg)	0.16 ml/Kg (12.5 mg/kg)	0.27 ml/Kg (6.7 mg/kg)	0.13 ml/Kg (6.7 mg/kg)

Pediatric patients weighing 40 kg and more should be dosed according to the adult.

Dosage in renal impairment (based on Amoxycillin component): as follows:

Adults :

- In mild impairment (creatinine clearance > 30 ml / min): no dosage adjustment is required.
- In moderate impairment (creatinine clearance 10-30 ml/min) : the dosage should be 250-500 mg every 12 hours.
- In severe impairment (creatinine clearance < 10 ml/min) : the dosage should be 250-500 mg every 24 hours.

Children : Similar reductions in dosage should be made for children.

CONTRAINDICATIONS

Hypersensitivity to penicillins.

WARNINGS

Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions. If any allergic reaction occurs, treatment should be discontinued and the appropriate therapy instituted. A low incidence of cross-allergy with cephalosporins may exist.

PRECAUTIONS

Dosage should be adjusted in patients with moderate or severe renal impairment. This medicament should be administered with caution in patients with severe hepatic dysfunction. Safety for the use in pregnancy has not yet been established. However, animal studies have shown no teratogenic effects. This medicament should be used during pregnancy only if clearly needed (FDA Pregnancy Category B). This medicament is excreted in breast milk in small quantities and should be used with caution in lactating mothers. Megamox-JPI suspensions contain aspartame and therefore care should be taken in phenylketonuria. Prolongation of bleeding time and prothrombin time have been reported in some patients receiving this medicament. Therefore, it should be used with care in patients on anti-coagulation therapy. As with other broad-spectrum antibiotics, this medicament may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

SIDE EFFECTS

As with Amoxycillin, they are uncommon and mainly of a mild and transitory nature. These include gastrointestinal disturbances (e.g. diarrhea, nausea, vomiting), and may be reduced by taking this medicament at the start of meals, hypersensitivity reactions (e.g. urticarial and erythematous rashes) may occur also. Hepatitis and cholestatic jaundice have been reported rarely and they are usually reversible. CNS effects have been seen very rarely. Convulsions may occur with impaired renal function or in those receiving high doses.

OVERDOSAGE

Problems of overdosage with this medicament are unlikely to occur. In case of overdosage, symptomatic treatment may be considered. This medicament may be removed from the circulation by haemodialysis.

PRESENTATION

Tablets

Megamox-JPI 1 g : Amoxycillin (as trihydrate) USP 875 mg and clavulanic acid (as potassium) USP 125 mg/tablet.

Megamox-JPI 625 mg : Amoxycillin (as trihydrate) USP 500 mg and clavulanic acid (as potassium) USP 125 mg/tablet.

Megamox-JPI 375 mg : Amoxycillin (as trihydrate) USP 250 mg and clavulanic acid (as potassium) USP 125 mg/tablet.

Suspension

Megamox-JPI 457 mg : Amoxycillin (as trihydrate) USP 400 mg and clavulanic acid (as potassium) USP 57 mg *.

Megamox-JPI 228 mg : Amoxycillin (as trihydrate) USP 200 mg and clavulanic acid (as potassium) USP 28.5 mg *.

Megamox-JPI 312 mg : Amoxycillin (as trihydrate) USP 250 mg and clavulanic acid (as potassium) USP 62.5 mg*.

Megamox-JPI 156 mg : Amoxycillin (as trihydrate) USP 125 mg and clavulanic acid (as potassium) USP 31.25 mg*.

Drops

Megamox-JPI Infant drops : Amoxycillin (as trihydrate) USP 50 mg and clavulanic acid (as potassium) USP 12.5 mg**.

* per 5 ml (after reconstitution).

** per 1 ml (after reconstitution).

Excipients (Tablets): Colloidal Anhydrous Silica, Sodium Starch Glycolate, Magnesium Stearate, Opadry white, Methylene Chloride, and Methanol.

Excipients (Suspension): Xanthan Gum, Succinic acid, Colloidal anhydrous silica, aspartame, Hydroxy propyl methyl cellulose, Golden Syrup, Orange flavor and syloid.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children

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