AMOXICILLIN

VAXMAN®
250 mg/5 mL Powder for Suspension
ANTIBACTERIAL
(PENICILLIN)

℞

FORMULATION
Each 5 mL (one teaspoonful) contains:
Amoxicillin (as trihydrate), USP..... 250 mg

PRODUCT DESCRIPTION
White to off-white to yellowish powder, milky orange flavored suspension upon reconstitution.

PHARMACODYNAMICS
Amoxicillin is a semi-synthetic aminopenicillin of the beta-lactam group of antibiotics. It has a broad spectrum of antibacterial activity against many Gram-positive and Gram-negative micro-organisms, acting through the inhibition of biosynthesis of cell mucopeptide. It is rapidly bactericidal and possesses the safety profile of penicillin.

PHARMACOKINETICS
Amoxicillin is well absorbed. Oral administration, usually at convenient three times a day dosage, produces high serum levels independent of the time at which food is taken. Amoxicillin gives good penetration into bronchial secretions and high urinary concentrations of unchanged antibiotic. Amoxicillin is not highly protein bound; approximately 18% of total plasma drug content is bound to protein. Amoxicillin diffuses readily into most body tissues and fluids, with the exception of the brain and spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins to penicillins and this may apply to Amoxicillin. The elimination half-life is approximately one hour. The major route of elimination for Amoxicillin is via the kidney. Approximately 60 to 70% of Amoxicillin is excreted unchanged in urine during the first six hours after administration of a standard dose. Amoxicillin is also partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to 10-25% of the initial dose. Concurrent administration of probenecid delays Amoxicillin excretion.

INDICATIONS
For the treatment of infections caused by susceptible strains of Gram-positive and Gram-negative organisms such as respiratory, gastrointestinal and genitourinary tract, skin and soft tissue infections.

DOSAGE AND MODE OF ADMINISTRATION
Adults and adolescents (>40 kg body weight):
The usual dosage covers a range from 750 mg to 3 g amoxicillin daily in three divided doses.
In some areas 1500 mg amoxicillin daily in three divided doses are recommended as the upper usual dose.

Special dosage recommendation
Acute exacerbation of chronic bronchitis in adults: 2 x 1 g per day.

Children (under 40 kg):
For infants and children oral suspensions containing amoxicillin are recommended.
The daily dosage for Children is 40 - 90 mg/kg/day in two to three divided doses* (not exceeding 3 g/day) depending on the indication, severity of the disease and the susceptibility of the pathogen.

*PK/PD data indicate that dosing three times daily is associated with enhanced efficacy, thus twice daily dosing is only recommended when the dose is in the upper range.

Children weighing more than 40 kg should be given the usual adult dosage.

Special dosage recommendation
Tonsillitis: 50 mg/kg/day in two divided doses.
Acute otitis media: In areas with high prevalence of pneumococci with reduced susceptibility to penicillins, dosage regimens should be guided by national/local recommendations.

Dosage for the prevention endocarditis
For the prevention of endocarditis, in patients not having general anaesthetic, 3 g amoxicillin are given orally in the hour preceding the surgical procedure, followed by (6 hours later) a further 3 g dose, if considered necessary.

For children: 50 mg amoxicillin/kg body weight given as a single dose one hour preceding the surgical procedure.

For further details and description of patients at risk local official guidelines for the prevention of endocarditis should be consulted.

Dosage in impaired renal function:
The dose should be reduced in patients with severe renal function impairment. In patients with a renal clearance of less than 30mL/min an increase in the dosage interval and a reduction in the total daily dose in recommended.

Adult (including elderly patients):

Creatinine clearance mL/min	Dose	Interval between administration
.> 30	No adjustment necessary	
10 - 3	500 mg	12 h
< 10	500 mg	24 h

In case of haemodialysis: 500 mg should be administered at the end of the procedure.

Renal impairment in children under 40 kg:

Creatinine clearance mL/min	Dose	Interval between administration
.> 30	Usual dose	No adjustment necessary
10 - 3	Usual dose	12 h (corresponding to 2/3 of the dose)
< 10	Usual dose	24 h (corresponding to 1/3 of the dose)

Dosage in impaired hepatic function:
No dose reduction is necessary as long as the renal function is not impaired.

Duration of therapy
In general the therapy should be continued for 2 to 3 days following the disappearance of symptoms. In β-haemolytic streptococcal infections the duration of therapy should be 6 - 10 days in order to achieve eradication of the organism.

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

Or as prescribed by the physician.

CONTRAINDICATIONS
Amoxicillin is penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (eg.penicillins, cephalosporins).

WARNING AND PRECAUTION
Before initiating therapy with Amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to beta lactam antibiotics.

Amoxicillin should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilli form rash has been associated with his condition following the use of Amoxicillin.

Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

Dosage should be adjusted in patients with renal impairment.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of Amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of Amoxicillin crystalluria.

Abnormal prolongation of prothrombin time [increased international normalized ratio (INR)] has been reported rarely in patients receiving Amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Effects on Ability to Drive and Use Machines: Adverse effects on the ability to drive or operate machinery have not been observed.

PREGNANCY and LACTATION
The safety of Amoxicillin for use in human pregnancy has not been established by well controlled studies in pregnant women. Reproduction studies have been performed in mice and rats at doses up to 10 times the human dose and these studies have revealed no evidence of impaired fertility or harm to the fetus due to Amoxicillin. Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment. 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.

DRUG INTERACTIONS
Probenecid decreases the renal tubular secretion of Amoxicillin. Concomitant use with Amoxicillin may result in increased and prolonged blood levels of Amoxicillin.

In common with other antibiotics, Amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral contraceptives.

Concurrent administration of allopurinol during treatment with Amoxicillin can increase the likelihood of allergic skin reactions. It is recommended that when testing for the presence of glucose in urine during Amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of Amoxicillin, false-positive readings are common with chemical methods.

In the literature, there are rare cases of increased international normalized ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of Amoxicillin. If co-administration is necessary, the prothrombin time or INR should be carefully monitored with the addition or withdrawal of Amoxicillin.

ADVERSE EFFECT
Gastrointestinal disturbances and rashes may occur. Small amount of Amoxicillin excreted in the milk may provoke allergic reactions in breastfeed infants.

OVERDOSE AND TREATMENT
Problems of overdosage with Amoxicillin are unlikely to occur. If ecountered, gastrointestinal effects such as nausea, vomiting and diarrhea 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 can be removed from the circulation by haemodialysis.

DIRECTIONS FOR RECONSTITUTION
Shake the bottle to loosen the powder. To make 60 mL reconstituted suspension, mix thoroughly the contents with 41 mL water and shake well until the powder is evenly suspended.
The reconstituted suspension is stable for 7 days at temperatures not exceeding 30°C and 14 days when refrigerated (2°C- 8°C).

SHAKE WELL BEFORE USE

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"
Seek medical attention immediately at the first sign of any adverse drug reaction.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY
Amber Glass Bottle x 60 mL (Box of 1's).

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

REGISTRATION NUMBER
DRP-10727

DATE OF FIRST AUTHORIZATION/ RENEWAL
June 28, 2012

DATE OF REVISION
JUNE 2022

Manufactured by:
JM TOLMANN LABORATORIES, INC.
#95 North Zuzuarregui St., Diliman, Q. C.

170 mm

105 mm

INSERT Required size:
105mm x 170mm
Required folding:
2 Folds crosswise
(facing the text)