

AMOXICILLIN
Trihydrate
VAXMAN®

100 mg/mL Powder for Suspension
Oral Drops
ANTIBACTERIAL
(Penicillin)

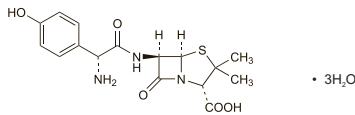


FORMULATION

Each mL contains:
Amoxicillin (as trihydrate), USP..... 100 mg

DESCRIPTION

Amoxicillin is a semi-synthetic penicillin a close chemical and a pharmacological relative of Ampicillin. The drug is stable in acid and is designed for oral use. The antimicrobial spectrum of Amoxicillin is essentially identical to that of Ampicillin with the important exception that Amoxicillin appears to be less effective than Ampicillin for Shigellosis. Amoxicillin is more rapidly and completely absorbed from the gastrointestinal tract than Ampicillin, which is the major difference between the two. Peak concentration in plasma is 2 to 2 ½ times greater for Amoxicillin than that of Ampicillin after oral administration of the same dose. Food does not interfere with absorption, perhaps because of more complete absorption of this congener.



A white, practically odourless crystalline powder. Slightly soluble in water and in methyl alcohol; insoluble in carbon tetrachloride, in chloroform, and in benzene. pH of a 0.2% solution in water is between 3.5 and 6.0.

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

INFANTS:

1-3 years old : 1 mL
7-12 months : 0.75 mL
1-6 months : 0.50 mL
< 1 month : 0.25 mL
All doses to be taken every eight (8) hours.
Or as prescribed by a physician.

PRECAUTIONS

Amoxicillin is contraindicated in patients known to be sensitive to penicillin and it should be used with caution on patients with known history of allergy to the drug.

DIRECTIONS FOR RECONSTITUTION

Shake the bottle to loosen the powder. To make 10 mL reconstituted suspension, mix thoroughly the contents with 7.0 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

ADVERSE EFFECT

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

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 with Dropper x 10 mL (Box of 1's)

STORAGE CONDITION

Store at temperatures not exceeding 30°C.

REGISTRATION NUMBER

DRP-10662

DATE OF FIRST AUTHORIZATION/RENEWAL

April 17, 2013

DATE OF REVISION

November 2021



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