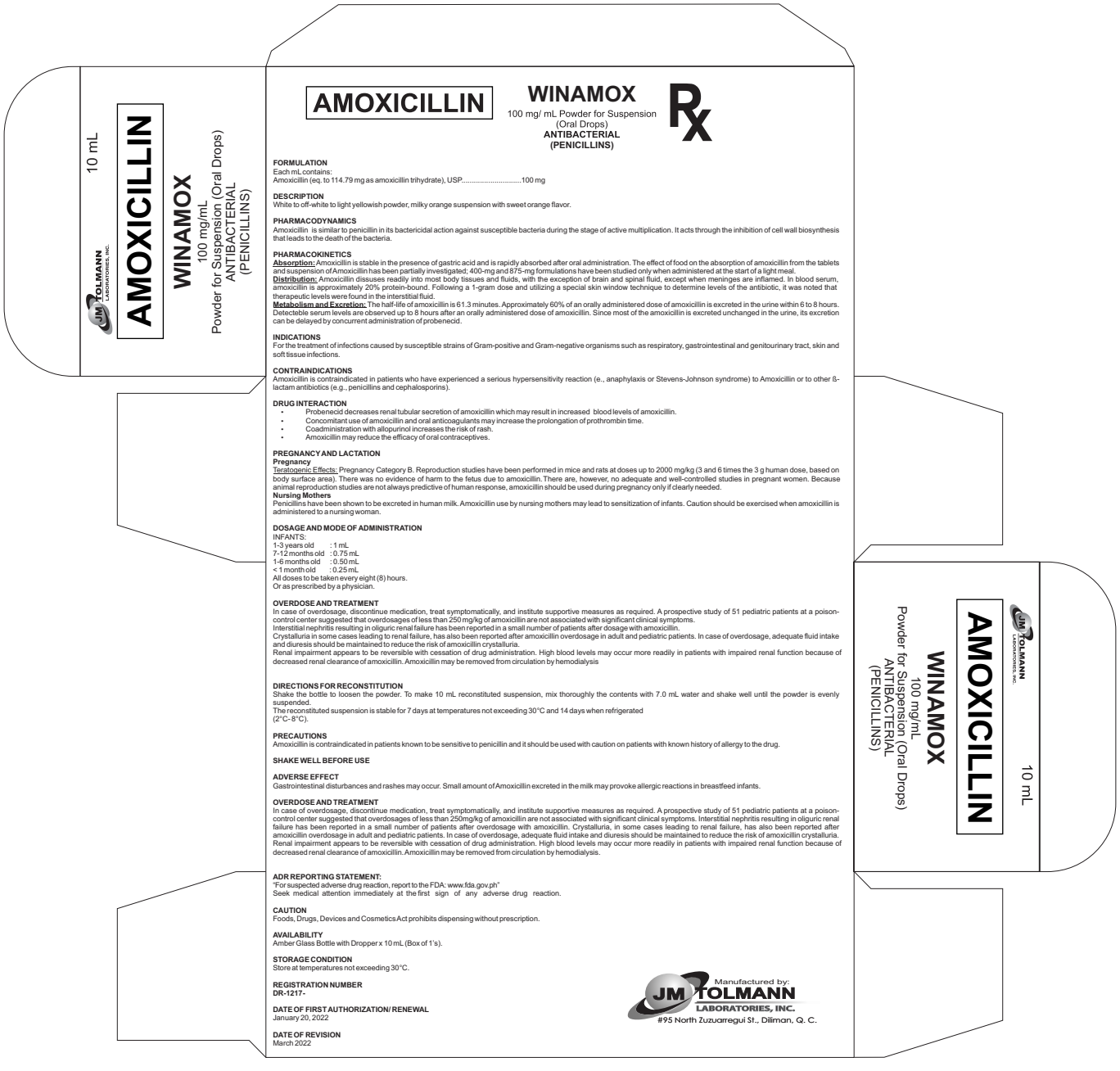
PACKAGING INSERT PRINTED ON THE INSIDE PANEL OF THE BOX



10 mL

JM TOLMANN LABORATORIES, INC.

AMOXICILLIN

WINAMOX

100 mg/mL

Powder for Suspension (Oral Drops)

ANTIBACTERIAL

(PENICILLINS)

AMOXICILLIN

WINAMOX

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

Rx

FORMULATION
Each mL contains:
Amoxicillin (eq. to 114.79 mg as amoxicillin trihydrate), USP.....100 mg

DESCRIPTION
White to off-white to light yellowish powder, milky orange suspension with sweet orange flavor.

PHARMACODYNAMICS
Amoxicillin is similar to penicillin in its bactericidal action against susceptible bacteria during the stage of active multiplication. It acts through the inhibition of cell wall biosynthesis that leads to the death of the bacteria.

PHARMACOKINETICS
Absorption: Amoxicillin is stable in the presence of gastric acid and is rapidly absorbed after oral administration. The effect of food on the absorption of amoxicillin from the tablets and suspension of Amoxicillin has been partially investigated; 400-mg and 875-mg formulations have been studied only when administered at the start of a light meal.
Distribution: Amoxicillin dissuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. In blood serum, amoxicillin is approximately 20% protein-bound. Following a 1-gram dose and utilizing a special skin window technique to determine levels of the antibiotic, it was noted that therapeutic levels were found in the interstitial fluid.
Metabolism and Excretion: The half-life of amoxicillin is 61.3 minutes. Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within 6 to 8 hours. Detectable serum levels are observed up to 8 hours after an orally administered dose of amoxicillin. Since most of the amoxicillin is excreted unchanged in the urine, its excretion can be delayed by concurrent administration of probenecid.

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.

CONTRAINDICATIONS
Amoxicillin is contraindicated in patients who have experienced a serious hypersensitivity reaction (e., anaphylaxis or Stevens-Johnson syndrome) to Amoxicillin or to other ß-lactam antibiotics (e.g., penicillins and cephalosporins).

DRUG INTERACTION
- Probenecid decreases renal tubular secretion of amoxicillin which may result in increased blood levels of amoxicillin.
- Concomitant use of amoxicillin and oral anticoagulants may increase the prolongation of prothrombin time.
- Coadministration with allopurinol increases the risk of rash.
- Amoxicillin may reduce the efficacy of oral contraceptives.

PREGNANCY AND LACTATION
Pregnancy
Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 2000 mg/kg (3 and 6 times the 3 g human dose, based on body surface area). There was no evidence of harm to the fetus due to amoxicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, amoxicillin should be used during pregnancy only if clearly needed.
Nursing Mothers
Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

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

OVERDOSE AND TREATMENT
In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. A prospective study of 51 pediatric patients at a poison-control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms.
Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after dosage with amoxicillin.
Crystalluria in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.
Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin. Amoxicillin may be removed from circulation by hemodialysis

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).

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.

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.

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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
DR-1217-

DATE OF FIRST AUTHORIZATION/ RENEWAL
January 20, 2022

DATE OF REVISION
March 2022

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

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