

DILOXANIDE FUROATE

DILFUR

500 mg Tablet
125mg/5mL Suspension

Amebicide

PRODUCT DESCRIPTION:

Diloxanide Furoate (Dilfur) is a white, round beveled edge, scored tablet in amber blister pack by 10's.

Diloxanide Furoate (Dilfur) suspension is an orange liquid with orange flavor. It comes in an amber glass bottle holding 60 mL of suspension.

FORMULATION:

Each 5mL (1 teaspoonful) contains:

Diloxanide Furoate, PP.....125 mg

Each tablet contains:

Diloxanide Furoate, BP.....500mg

INDICATION:

For the treatment of intestinal amebiasis. It is given alone in the treatment of asymptomatic cyst passers and with an amebicide that acts in the tissues.

PHARMACODYNAMICS and PHARMACOKINETICS:

Diloxanide Furoate is hydrolyzed before absorption from the gastro-intestinal tract. The resulting diloxanide is readily absorbed and excreted mainly in the urine; less than 10% of the dose appears in the feces.

DOSAGE and METHOD OF ADMINISTRATION:

Tablet: 1 tablet every 8 hours for 10 days.

Suspension:

Adult: 1 tablespoon (15mL) every 6 hours daily. To be administered for a period of 10 days.

Children: Children weighing more than 25 kg may be given 20mg/kg daily, in divided doses, for 10 days. The course of treatment may be repeated if necessary.

Or as prescribed by a physician.

CONTRAINDICATION:

Diloxanide Furoate (Dilfur) is contraindicated in patients who have exhibit a history of hypersensitivity reaction to diloxanide furoate or any of its components.

PRECAUTIONS and WARNINGS:

Diloxanide Furoate (Dilfur) must be administered cautiously to patient with hepatic impairment.

PREGNANCY and LACTATION:

The safety of Diloxanide Furoate (Dilfur) in pregnant and lactating women has not been established and should therefore not be used in these patients.

INTERACTIONS:

Diloxanide Furoate (Dilfur) has no known drug interaction.

ADVERSE DRUG REACTION:

Diloxanide Furoate (Dilfur) is generally well tolerated with only occasional mild adverse events which include flatulence, nausea, vomiting, diarrhea, pruritis and urticaria.

OVERDOSE AND TREATMENT:

For overdosage of Diloxanide Furoate (Dilfur) give supportive measures and symptomatic treatment.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C. Keep the product out of sight and reach of children.

DOSAGE FORMS and PACKAGING AVAILABLE:

Available in Amber Blister Pack x 10's (Box of 100's)

Available in Amber Glass bottle x 60mL (Box of 1's)

CAUTION:

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

MANUFACTURER and MARKETING AUTHORIZATION HOLDER:

ST. MARTIN PHARM LAB CO.

55 Lakandula St., Parang, Marikina City

REGISTRATION NUMBER:

Tablet: DRP – 1127

Suspension: DRP - 3697

DATE OF FIRST AUTHORIZATION:

Tablet : April 6, 2011

Suspension : April 4, 2011

DATE OF RENEWAL OF THE AUTHORIZATION:

Tablet : 09/24/2024

Suspension : 04/06/2024

DATE OF REVISION OF PACKAGE INSERT: March 4, 2019

“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.