

METRONIDAZOLE

RODAZID™

125 mg per 5 mL Suspension

ANTIPROTOZOAL

FORMULATION:

Each 5 mL (1 teaspoonful) contains:
Metronidazole (as Benzoate) 125 mg

PHARMACOLOGICAL ACTIONS:

Metronidazole is a nitroimidazole compound that possesses antibacterial and antiprotozoal activities. It is effective against anaerobic protozoal parasites and against a broad range of anaerobic bacteria.

Metronidazole has a strong antibacterial activity against anaerobic cocci, anaerobic Gram-negative bacilli and anaerobic spore-forming Gram-positive bacilli.

Bactericidal actions of metronidazole against obligate anaerobes include its penetration into the bacterial cell, reductive activation and toxic effect of the reduced intermediate products. The intermediate product of metronidazole reduction causes cell death through its interaction with bacterial DNA.

PHARMACOKINETICS:

After oral intake, metronidazole is readily absorbed from the gastrointestinal tract, widely distributed in body tissues, and penetrates well into the cerebrospinal fluid. The presence of food in the stomach may delay its absorption. Maximum concentration occurs in the serum after about one hour. It has a plasma half-life of about 7-8 hours. Metronidazole is metabolized mainly in the liver.

About 50-75% is excreted in the urine as metabolites, including an acid oxidation product, a hydroxy derivative and a glucuronide.

Metronidazole diffuses across the placenta and is found in breast milk of nursing mothers.

INDICATIONS:

Used in the treatment of susceptible protozoal infections and in the treatment and prophylaxis of anaerobic bacterial infections.

DOSAGE AND ADMINISTRATION:

SUSPENSION FOR CHILDREN:

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| Trichomoniasis: 7-day course | 1-3 years old 3-7 years old | 50 mg three times daily 100 mg three times daily or 15 mg/kg body weight per day in divided doses |
| Giardiasis: | | Proportional as for ameobiasis; or 15 mg/kg in divided doses |
| Amoebiasis: | 1-3 years old 3-7 years old 7-10 years old | One quarter One third One half the adult dose; or 35-50 mg/kg body weight daily in divided doses has been used |
| Anaerobic infections: | | 7.5 mg/kg body weight per day every 8 hours |

Or as prescribed by the physician.

ADVERSE EFFECTS:

Side effects of metronidazole include gastrointestinal discomfort, anorexia, nausea, coated tongue or metallic taste, dry mouth and unpleasant taste, headache, pruritus, skin rash, and less frequently vomiting, diarrhea, weakness, vertigo, ataxia, depression, and darkening of the urine.

Occasionally, there may be temporary moderate leucopenia. Peripheral neuropathy may occur after prolonged therapy with high doses.

CONTRAINDICATIONS/PRECAUTIONS:

Metronidazole should not be used in patients with blood dyscrasias or with active disease of the central nervous system. Its use should be avoided during pregnancy.

As metronidazole is metabolized in the liver, it may accumulate in hepatic insufficiency so dosage should be adjusted in patients with active liver disease.

Women taking metronidazole should not breast-feed their babies. Metronidazole should not be given with alcohol, because a disulfiram-like reaction may be provoked in some individuals.

DRUG INTERACTIONS:

Metronidazole enhances the anticoagulant effect of warfarin. Metronidazole should not be given in patients taking high doses of lithium as it may precipitate lithium toxicity.

Drugs that inhibit hepatic microsomal metabolism can increase plasma levels of metronidazole.

Cimetidine can increase plasma concentrations of metronidazole and might increase the risk of neurological side effects.

WARNING:

Metronidazole has shown to be carcinogenic in mice and possibly in rats. Unnecessary use of the drug should therefore be avoided.

CAUTION:

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

AVAILABILITY:

Amber Glass Bottle x 60 mL and 120 mL (Box of 1's) DR-XY22116

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

“For suspected adverse drug reactions, report to the FDA: www.fda.gov.ph”



Manufactured for:

PNSV ASIA CORPORATION

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#16 Scout Tuazon cor. Roces Ave., Quezon City
Metro Manila, Philippines
by: Lloyd Laboratories, Inc.
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City of Malolos, Bulacan

Date of Renewal of the Authorization: 13 April 2019

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