Metronidazole

RODAZID

500 mg Tablet

Antiprotozoal

FORMULATION:

Each tablet contains:

Metronidazole, USP.....500 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 organisms, and anaerobic spore-forming gram-positive organisms.

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. It appears in most body tissues and fluids including bone, liver, bile, cerebral and liver abscess, saliva, seminal fluid and vaginal secretions. Concentrations are

achieved similar to those in plasma. Absorption of metronidazole may be delayed but is not reduced overall by food. Maximum concentration occurs in the serum after about one hour. Metronidazole has an elimination half-life of about 8 hours. Its half-life is said to be longer in neonates and in patients with severe hepatic impairment. Metronidazole is metabolized mainly in the liver.

Majority of the dose of metronidazole is excreted in the urine mainly as metabolites, including an acid oxidation product, a hydroxy derivative and a glucuronide. A small amount appears in the feces.

Metronidazole diffuses across the placenta and rapidly enters the fetal circulation. It is found in breast milk of nursing mothers.

INDICATIONS:

Used in the treatment of amoebiasis, balantidiasis and Blastocystis hominis infection, giardiasis, trichomoniasis, bacterial vaginosis, and acute necrosing ulcerative gingivitis, as well as prevention of postoperative anaerobic bacterial infection, peptic ulcer diseases, leg ulcers and pressure sores, and anaerobic infections.

DOSAGE AND ADMINISTRATION:

FOR ADULTS:

Amoebiasis:	400 mg – 800 mg three times daily for 5 – 10 days; or 1.5 – 2.5 g as a single dose daily for 2 or 3 days; or as prescribed by the physician.
Balantidiasis and Blastocystis hominis infections:	Similar to those used in amoebiasis; or as prescribed by the physician.
Giardiasis:	2 g once daily for 3 successive days; or 400 mg three times daily for 5 days; or 500 mg twice daily for 7 – 10 days; or as prescribed by the physician.

Trichomoniasis:	2 g as a single dose; or 2-day course of 800 mg in AM and 1.2 g in PM; or 7-day course of 600 mg – 1 g daily in 2 or 3 divided doses; or as prescribed by the physician.
Bacterial Vaginosis	400 mg – 500 mg twice daily for 5 – 7 days; or 2 g as a single dose; or as prescribed by the physician.
Acute Necrosing Ulcerative Gingivitis:	200 mg – 250 mg every 8 hours for 3 days; or as prescribed by the physician.
Prevention of Postoperative Anaerobic Bacterial Infections:	400 mg every 8 hours, 24 hours before surgery followed postoperatively by infusion or rectal administration until oral therapy is possible; or as prescribed by the physician.
Peptic Ulcer Disease:	400 mg twice daily (except when given in combination with Omeprazole and Amoxicillin) 400 mg three times daily for 1 week; or as prescribed by the physician.
Leg Ulcers and Pressure sores:	400 mg every 8 hours for 7 days; or as prescribed by the physician.
Anaerobic Infections:	800 mg initially then 400 mg every 8 hours for 7 days; or 500 mg every 8 hours; or as prescribed by the physician.

ADVERSE EFFECTS:

The most common adverse effects of metronidazole are gastrointestinal disturbances mostly nausea and unpleasant metallic taste. Diarrhea, constipation and vomiting may also be experienced. A furred or coated tongue, glossitis and stomatitis may be associated with overgrowth of Candida sp. There were rare reports of antibiotic-associated colitis. The adverse effects are generally dose-related.

Headache, weakness, dizziness, drowsiness, ataxia, dysarthria, insomnia, changes in mood or mental state such as depression and confusion may occur, seizure and peripheral neuropathy may occur after prolonged therapy with high doses of metronidazole.

Temporary moderate leucopenia, thrombocytopenia, skin rashes, urticaria, and pruritus may occur. Occasionally gynecomastia, erythema multiforme, angioedema, and anaphylaxis have been reported rarely.

Other adverse effects include optic neuropathies, urethral discomfort, darkening of urine, elevated liver enzymes, cholestatic hepatitis and jaundice.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:

Metronidazole should not be given to patients with history of hypersensitivity to imidazoles.

Metronidazole should not be taken more than the recommended dosage and duration. In patients given metronidazole for more than 10 days, clinical and laboratory monitoring is advise. Blood test should be monitored regularly especially the leucocyte count.

Special warning is given for patients with active or chronic severe peripheral and central nervous system diseases. As metronidazole is metabolized in the liver, doses should be reduced in patients with severe hepatic impairment.

Patients should not drink alcoholic beverages while taking metronidazole.

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

PREGNANCY AND LACTATION:

Metronidazole can readily cross the placenta and should be avoided during pregnancy.

Metronidazole is distributed into breast milk; unnecessary exposure to the drug should be avoided. It is recommended to stop breast feeding for 12-24 hours when single-dose therapy is used. There are no specific recommendations available for long-term therapy.

DRUG INTERACTIONS:

Metronidazole may impair the metabolism or excretion of warfarin, phenytoin, lithium, ciclosporin and fluorouracil. The metabolism of metronidazole might be accelerated by phenytoin. Phenobarbital decreases the plasma concentration of

metronidazole. Cimetidine increases the plasma concentrations of metronidazole and might increase the risk of neurological adverse effects.

Alcohol, when taken with metronidazole, may provoke a disulfiram-like reaction in some patients. Acute psychoses or confusion have been reported.

OVERDOSE AND TREATMENT:

There have been reported cases of accidental overdoses and suicidal attempts with metronidazole up to 12 grams. However there is no specific treatment. Symptomatic and supportive management should be administered.

CAUTION:

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

AVAILABILITY:

Alu PVC Blister Pack of 10's (Box of 100's) DR-XY18633

STORE AT TEMPERATURES NOT EXCEEDING 30ºC.

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"

Pnsv Asia

Manufactured for:

PNSV ASIA CORPORATION

4/F S.V. More Group Corporate Center

#16 Scout Tuazon cor. Roces Ave., Quezon City

Metro Manila, Philippines

by: **Lloyd Laboratories, Inc.**

#10 Lloyd Ave., First Bulacan Industrial City

City of Malolos, Bulacan

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