30 mm

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For the use only of a Registered Medical Practitioner or Hospital or a Laboratory
METRONIDAZOLE ORAL SUSPENSION BP

Unique's
metrogyl®
SUSPENSION 200mg/5mL

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PRODUCT DESCRIPTION
Light orange coloured, viscous suspension having characteristics fruity flavour with sweet taste.

COMPOSITION
Each 5mL (teaspoonful) contains:-
Metronidazole Benzoate BP
Equivalent to Metronidazole ……. 200mg
In a flavoured syrup base.

PRESERVATIVES
Sodium Methyl Hydroxybenzoate
Sodium Propyl Hydroxybenzoate
Sorbic Acid

PHARMACODYNAMICS
Metronidazole is an effective, broad-spectrum antiprotozoal and antibacterial drug from the group of nitroimidazole. It is effective for the clinical treatment of patients with pyo-inflammatory diseases.

PHARMACOLOGICAL ACTIONS
Metronidazole diffuses into aerobic and anaerobic bacteria equally well, but in the former it remains unchanged whilst in the latter it is reduced. As a result of biochemical reduction in the cell, the concentration of unchanged drug is reduced and this probably creates a gradient which promotes further uptake of the drug into anaerobic organisms. The nitro group of Metronidazole accepts electrons from electron-transport proteins and diverts them from normal energy yielding pathways. Oxygen markedly reduced the uptake and specifity of Metronidazole for anaerobes may be because their redox processes are different from those of aerobes; It has been assumed that the product of reduction of the nitro group of Metronidazole interacts with DNA with ultimate inhibition of nucleic acid synthesis and subsequent cell death. Moreover Metronidazole has been shown to inhibit DNA synthesis and degrade existing DNA in Clostridium bifermentans.

PHARMACOKINETICS
Metronidazole is completely and promptly absorbed after oral administration. Half- life is about 8 Hrs, and its volume of distribution is approximately that of body water. About 10% of the drug is bound to plasma protein. Metronidazole penetrates well into body tissues and fluids. Therapeutics concentration is also achieved in the cerebrospinal fluid.
Both unchanged metronidazole & several metabolites are excreted in various proportions in the urine after oral administration of the parent compound. The liver is the main site of metabolism and this accounts for over 50% of the systemic clearance of Metronidazole. The 2 principal metabolites result from oxidation of side chains, both have antitrichomonal activity. The major route of elimination of Metronidazole and its metabolites is via the urine (60% to 80% of the dose) with faecal excretion accounting for 6% to 15% of the dose.
Decreased renal function does not alter the single dose pharmacokinetics of Metronidazole. However, plasma clearance of Metronidazole is decreased in patients with decreased liver function.

INDICATION
Amoebiasis, Giardiasis
Amoebic liver abscess
Anaerobic Bacterial Infections

DOSAGE
Children: 35 to 50 mg /kg /24 hours, divided into three doses, orally for 10 days.

CONTRAINDICATION
Metrogyl is contraindicated in patients with a prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives.

WARNING AND PRECAUTIONS
General: Patients with severe hepatic disease metabolize metronidazole slowly, with resultant accumulation of metronidazole and its metabolites in a plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously.
Mutagenicity studies: Although metronidazole has shown mutagenic activity in a number of in vitro assay systems. Studies in mammals (in vivo) have failed to demonstrate a potential for genetic damage.
Convulsive Seizures and Peripheral Neuropathy: Convulsive seizures and peripheral neuropathy, the latter characterized mainly b numbness or paraesthesia of an extremity, have been reported in patients treated with metronidazole. The appearance of abnormal neurologic signs demands the prompt discontinuation of Metrogyl therapy. Metrogyl should be administered with caution to patients with central nervous system diseases.

Cases of severe hepatotoxicity/acute hepatic failure including cases with a fatal outcome with very rapid onset after treatment initiation in patients with Cockayne, syndrome have been reported with products containing Metronidazole for systemic use. In this population, Metronidazole should therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. Liver function tests must be performed just prior to the start of therapy, throughout and after end of treatment until liver function tests become markedly elevated during treatment, the drug should be discontinued.
Patients with Cockayne syndrome should be advised to immediately report any symptoms of potential liver injury to their physician and stop taking Metronidazole.

INTERACTIONS WITH OTHER MEDICAMENTS
Metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other oral coumarin anticoagulants, resulting in a prolongation of prothrombin time. This possible drug interaction should be considered when Metronidazole is prescribed for patients on this type of anticoagulant, therapy.
The simultaneous administration of drugs that induce microsomal liver enzymes, such as phenytoin or phenobarbital, may accelerate the elimination of metronidazole, resulting in reduced plasma levels; impaired clearance of phenytoin has also been reported.
The simultaneous administration of drugs that decrease microsomal liver enzyme activity, such as cimetidine, may prolong the half-life and decrease plasma clearance of metronidazole. In patients stabilized on relatively high doses of lithium, short-term Metronidazole therapy has been associated with elevation of serum lithium and in a few cases, signs of lithium toxicity. Serum lithium and serum creatinine levels should be obtained several days after beginning metronidazole to detect any increase that may precede clinical symptoms of lithium intoxication.
Alcoholic beverages should not be consumed during Metronidazole therapy and for at least one day afterward because abdominal cramps, nausea, vomiting, headaches, and flushing may occur.
Psychotic reactions have been reported in alcoholic patients who are using metronidazole and disulfiram concurrently. Metronidazole should not be given to patients who have taken disulfiram within the last two weeks.

SIDE EFFECTS
The following reactions have also been reported during treatment with Metrogyl (metronidazole)
Mouth: A sharp, unpleasant metallic taste is not unusual. Furry tongue, glossing and stomatiis have occurred; these may be associated with a sudden overgrowth of Candida which may occur during effective therapy.
Hemopoietic: Reversible neutropenia (leukopenia); rarely, reversible thrombocytopenia.
Cardiovascular: Flattening of the T-wave may be seen in electrocardiographic tracings.
Central Nervous Systems: Convulsive seizures, peripheral neuropathy, dizziness, vertigo, incoordination, ataxia, confusion, irritability, depression, weakness and insomnia.
Hypersensitivity: Urticaria, erythematous rash, flushing, nasal congestion, dryness of the mouth (of vagina or vulva) and fever.
Renal: Dysuria, cystitis, polyuria, incontinence and a sense of pelvic pressure, Instances of darkened urine have been reported and seen to have no clinical significance.

Overdose and Treatment
There is no human experience with Overdosage of Metronidazole. The acute oral toxicity of the metronidazole formulation was determined to be greater than Sgfkg (The highest dosage given) in the Albino rats.
Single oral doses of metronidazole, up to 15 g, have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting, and ataxia.
Oral metronidazole has been studies as a radiation sensitizer in the treatment of malignant tumours.
Neurotoxic effects, including seizures and peripheral neuropathy, have been reported after 5 to 7 days of doses of 6 to 10 for every other day.
Treatment: There is no specific antidote for Metronidazole overdose; therefore, management of the patient should consist of symptomatic and supportive therapy.

STORAGE
Store below 30°C.Protect from light.

SHELF LIFE: 48 Months

PRESENTATION: 100mL Bottles.

Manufactured by:
UNIQUE PHARMACEUTICAL LABORATORIES
(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot No. 215-216, G.I.D.C. Industrial Area, Panoli-394 116, Gujarat, India
® Regd. Trade Mark

Product Registration Holder and Imported by:
Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur, Malaysia.

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155 mm

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Date: 17.11.2023
Artist: Shrikant