METRO

Metronidazole

COMPOSITION

Metro 400 Tablet : Each film coated tablet contains Metronidazole BP 400 mg.
Metro Suspension: Each 5 ml suspension contains 200 mg of Metronidazole as Benzoyl Metronidazole.

PHARMACOLOGY

Metronidazole is an antimicrobial drug that is primarily active against obligate anaerobic microorganisms, both bacteria and protozoa. The 5-nitro group undergoes reductive transformation to an active intermediate which then exerts an inhibitory or lethal effect against DNA. Not only is DNA synthesis inhibited but the reduced metabolite also causes a loss of the helical structure of DNA with subsequent DNA strand breakage. In vitro, metronidazole demonstrates a consistently rapid bactericidal effect with the minimal bactericidal concentration approximating very closely to the minimal inhibitory concentration.

INDICATIONS

1) All forms of amoebiasis (intestinal and extra-intestinal disease including liver abscess and that of symptomless cyst passers), 2) Trichomoniasis, 3) Giardiasis, 4) Bacterial vaginosis, 5) Acute ulcerative gingivitis, 6) Anaerobic infections including septicaemia, bacteremia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, pelvic abscess, pelvic cellulitis, etc., 7) Anaerobically-infected leg ulcers and pressure sores, 8) Acute dental infections (e.g., acute pericoronitis and acute apical infections), 9) Surgical prophylaxis (prevention of postoperative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci), 10) Chronic symptomatic peptic ulcer disease (as an agent of triple therapy to eradicate H. pylori-the most important etiological factor of peptic ulcer).

DOSAGE AND ADMINISTRATION

Indication	Duration of treatment (Days)	Adults & Children over 10 years	Children		
			7-10 Years	3-7 Years	1-3 Years
Trichomoniasis **	7	200mg t.i.d or 400mg b.i.d	100mg t.i.d	100mg b.i.d	50mg t.i.d
	2	800mg in the morning and 1.2g at night	-	-	-
	1	2gm as a singe dose	-	-	-
Invasive intestinal amoebiasis	5	800mg t.i.d	400mg t.i.d	200mg q.i.d	200mg t.i.d
Extra intestinal amoebiasis(including Liver abcess) and symptomless amoebic cyst passers	5-10	400-800 mg t.i.d	200-400 mg t.i.d	100-200 mg t.i.d	100-200 mg t.i.d
Giardiasis	3	2.0gm Once daily	1.0gm once daily	600-800mg once daily	500mg once daily
Acute Ulcerative gingivitis.	3	200 mg t.i.d	100mg t.i.d	100mg b.i.d	50mg b.i.d
Acute dental infection.	3-7	200 mg t.i.d	-	-	-
Bacterial Vaginosis.	7 1	400mg b.i.d 2.0gm as a single dose	-	-	-
Leg ulcers & pressure sores	7	400 mg t.i.d	-	-	-
Anaerobic infections	7	800mg intially and then 400mg b.i.d	7.5mg/kg t.i.d	7.5mg/kg t.i.d	7.5mg/kg t.i.d
Surgical prophylaxis	-	400mg t.i.d started 24 hours before surgery	7.5mg/kg t.i.d	7.5mg/kg t.i.d	7.5mg/kg t.i.d

** Trichomoniasis : Concomitant treatment of sexual partner is recommended

CONTRAINDICATIONS AND PRECAUTIONS

Metronidazole is contraindicated in patients with a prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives. Metronidazole should not be used in pregnancy or should be used during pregnancy only if no alternative agent is available. Under the circumstances, high-dosage regimens are not recommended. Metronidazole should be avoided especially during the first trimester. Since metronidazole is excreted into breast milk, breast feeding should be discontinued during and for 2 days after therapy with metronidazole. Vaginitis due to organisms other than T. vaginalis does not respond to metronidazole; Disulfiram like reaction with alcohol ; Hepatic impairment.

SIDE EFFECTS

Metallic taste, furred tongue, nausea, vomiting, diarrhoea, drowsiness, rashes and mild reversible leukopenia may be observed during treatment. It is thus a relatively safe drug although when used in large doses over several months a few cases of severe peripheral neuropathy have occurred.

DRUG INTERACTIONS

Metronidazole has been found to interact with alcohol, nicoumalone and warfarin, phenytoin, phenobarbitone, fluorouracil, disulfiram, lithium and cimetidine.

USE IN PREGNANCY AND LACTATION

When metronidazole has been administered during pregnancy, no adverse effects have been noted in the mother or foetus. However, it is recommended that metronidazole not be given during the first trimester of pregnancy and avoided during the later trimesters if possible. If use is deemed necessary, short high-dose regimen is recommended. The efficacy of metronidazole in serious anaerobic infections has to be weighed against potential, but unproved, mutagenic and teratogenic effects. From limited data, metronidazole appears to cross the placenta, as would be expected from its lipid solubility. Metronidazole penetrates well into breast milk. If exposure of the neonates to metronidazole is to be avoided, breast-feeding should be delayed until 48 hours after discontinuing metronidazole in the mother.

STORAGE

Store in a cool (below 30° c) & dry place (below 65% RH), protect from light.

PACKAGING

Metro 400 tablet: Each box contains 10 x 10's tablet in blister pack.
Metro Suspension: Each box contains a bottle having 60 ml Suspension.

Manufactured by

ZISKA PHARMA

Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh