

Clozyl[®]

Metronidazole

COMPOSITION:

Clozyl[®] Tablet : Each film coated tablet contains Metronidazole BP 400 mg.

Clozyl[®] Suspension : Each 5 ml suspension contains Benzoyl Metronidazole BP equivalent to Metronidazole 200 mg.

PHARMACOLOGY:

Metronidazole a nitroimidazole has an extremely broad spectrum antiprotozoal and antimicrobial activities, with high activity against anaerobic bacteria and protozoa. Metronidazole is usually completely and rapidly absorbed after oral administration. The half-life in plasma is about 8 hours. About 10% of the drug is bound to plasma proteins. Metronidazole penetrates well into body tissues and fluids. The liver is the main site of metabolism. Both unchanged Metronidazole and metabolites are excreted in various proportions in the urine after oral administration.

INDICATION:

Metronidazole is indicated for -

- All forms of amoebiasis (intestinal and extra-intestinal disease including liver abscess and that of symptomless cyst passers)
- Trichomoniasis
- Giardiasis
- Bacterial vaginosis
- Acute ulcerative gingivitis
- Anaerobic infections including septicaemia, bacteraemia, peritonitis, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis etc.
- Anaerobically-infected leg ulcers and pressure sores
- Acute dental infections (e.g. acute pericoronitis and acute apical infections)
- Surgical prophylaxis (prevention of post-operative infections due to anaerobic bacteria
- Chronic symptomatic peptic ulcer disease (as an agent of triple therapy to eradicate H. pylori-the most important aetiological factor of peptic ulcer).

DOSE & ADMINISTRATION:

Indication	Duration of Dosage in days	Adult & Children (Over 10 years)	Children		
			7-10 years	3-7 years	1-3 years
Trichomoniasis	7	200 mg t.i.d or 400 mg b.i.d	100 mg t.i.d	100 mg t.i.d	50 mg t.i.d
	2	800 mg in the morning and 1.2 gm at night
	1	2.0 gm as s singel dose
Invasive intestinal amoebiasis	5	800 mg t.i.d	400 mg t.i.d	200 mg q.i.d	200 mg t.i.d
Extra intestinal amoebiasis (including liver abscess) and symptomless amoebic cyst passers	5 - 10	400-800 mg t.i.d	200-400 mg t.i.d	100-200 mg q.i.d	100-200 mg t.i.d
Giardiasis	3	2.0 gm once daily	1.0 gm once daily	600-800 mg once daily	500 mg once daily
Acute ulcerative gingivitis	3	200 mg t.i.d	100 mg t.i.d	100 mg b.i.d	50 mg t.i.d
Acute dental infections	3 - 7	200 mg t.i.d
Bacterial vaginosis	5 - 7	400-500 mg twice daily
	1	2.0 gm as a single dose
Leg ulcers and pressure sores	7	400 mg t.i.d
Anaerobic infections	7	Either 400 mg every 8 hours or 500 mg every 8 hours	7.5 mg/kg t.i.d	7.5 mg/kg t.i.d	7.5 mg/kg t.i.d
Surgical prophylaxis	As per surgeons recommendation	400-500 mg 24 hours before surgery : up to 3 further doses of 400 mg may be given every 8 hours for high-risk procedure	7.5 mg/kg t.i.d	7.5 mg/kg t.i.d	7.5 mg/kg t.i.d

CONTRA-INDICATION:

Human hypersensitive to Metronidazole. It should be avoided in pregnant womens, especially in the first trimester and it should not be used in lactating human.

WARNING AND PRECAUTION:

Patients with severe hepatic disease metabolize Metronidazole slowly, with resultant accumulation of Metronidazole and its metabolites in the plasma. Accordingly for such patients, doses below those usually recommended should be administered cautiously.

SIDE EFFECTS:

Vomiting, Metallic taste, Nausea, Diarrhoea, Drowsiness, Rashes may be observed during treatment.

USE IN PREGNANCY & LACTATION:

Not recommended during first & later trimesters. Breast feeding should be delayed until 48 hours after discontinuing Metronidazole in the mother.

USE IN CHILDREN & ADOLESCENTS:

Recommended by the consultaion with physicians.

DRUG INTERACTION:

Metronidazole interacts with Warfarin, Phenytoin, Phenobarbitone, Fluorouracil, Disulfiram, Lithium, Cimetidine etc.

OVERDOSE:

Single oral doses of Metronidazole, up to 15 gm, have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting and ataxia. Oral Metronidazole has been studied as a radiation sensitizing agent in the treatment of metronidazole tumors. Neurotoxic effects including seizures and peripheral neuropathy have been reported after 5 to 7 days of doses of 6 to 10.4 g every other day.

Treatment: There is no specific antidote for Metronidazole overdose.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Clozyl[®] Tablet : Each box contains 10x10's Tablets in Alu-PVC blister pack.

Clozyl[®] Suspension : Each bottle contains 60 ml Suspension with a 10 ml measuring cup.



Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0052