SPMC

METRAONIDAZOLE TABLETS USP 200 mg
METRAONIDAZOLE TABLETS USP 400 mg

PRESENTATION:

METRONIDAZOLE TABLETS USP 200 mg

Packs: 500 /1000Tablets bulk / 10X10 Blister

Pink color round biconvex tablets SPMC letter one side and breck notch on reverse. contains Metronidazole 200 mg.

METRONIDAZOLE TABLETS USP 400 mg
Packs: 500 Tablets bulk / 10X10 Blister
Each Oblong (16.6mm x7.9mm) Pink colored tablets with "SPMC" letters in one side & score mark in other side contains Metronidazole 400 mg.

INDICATION & DOSE:

Anaerobic infections
BY MOUTH
Child 1 month: 7.5 mg/kg every 12 hours usually treated for 7 days (for 10–14 days in Clostridium difficile infection)
Child 2 months–11 years: 7.5 mg/kg every 8 hours (max. per dose 400 mg) usually treated for 7 days (for 10–14 days in Clostridium difficile infection)
Child 12–17 years: 400 mg every 8 hours usually treated for 7 days (for 10–14 days in Clostridium difficile infection)
Adult: 400 mg every 8 hours, alternatively 500 mg every 8 hours usually treated for 7 days (for 10–14 days in Clostridium difficile infection)
BY RECTUM
Child 1–11 months: 125 mg 3 times a day for 3 days, then 125 mg twice daily, for usual total treatment duration of 7 days
Child 1–4 years: 250 mg 3 times a day for 3 days, then 250 mg twice daily, for usual total treatment duration of 7 days
Child 5–9 years: 500 mg 3 times a day for 3 days, then 500 mg twice daily, for usual total treatment duration of 7 days
Child 10–17 years: 1 g 3 times a day for 3 days, then 1 g twice daily, for usual total treatment duration of 7 days
Adult: 1 g 3 times a day for 3 days, then 1 g twice daily, for usual total treatment duration of 7 days
Helicobacter pylori eradication; in combination with clarithromycin and esomeprazole; or in combination with clarithromycin and lansoprazole; or in combination with amoxicillin and lansoprazole; or in combination with clarithromycin and omeprazole; or in combination with clarithromycin and pantoprazole; or in combination with clarithromycin and rabeprazole
BY MOUTH
Adult: 400 mg twice daily
Helicobacter pylori eradication; in combination with amoxicillin and omeprazole
BY MOUTH
Adult: 400 mg 3 times a day
Fistulating Crohn's disease
Adult: 10–20 mg/kg daily in divided doses, usual dose 400–500 mg 3 times a day usually given for 1 month but no longer than 3 months because of concerns about peripheral neuropathy.
Leg ulcers and pressure sores
BY MOUTH
Adult: 400 mg every 8 hours for 7 days
Bacterial vaginosis (notably Gardnerella vaginalis infection)
Adult: 400–500 mg twice daily for 5–7 days, alternatively, 2 g for 1 dose
Pelvic inflammatory disease
BY MOUTH
Adult: 400 mg twice daily for 14 days
Acute ulcerative gingivitis
BY MOUTH
Child 1–2 years: 50 mg every 8 hours for 3 days
Child 3–6 years: 100 mg every 12 hours for 3 days
Child 7–9 years: 100 mg every 8 hours for 3 days
Child 10–17 years: 200–250 mg every 8 hours for 3 days
Adult: 400 mg every 8 hours for 3 days
Acute oral infections
BY MOUTH
Child 1–2 years: 50 mg every 8 hours for 3–7 days
Child 3–6 years: 100 mg every 12 hours for 3–7 days
Child 7–9 years: 100 mg every 8 hours for 3–7 days
Child 10–17 years: 200–250 mg every 8 hours for 3-7 days
Adult: 400 mg every 8 hours for 3–7 days
Surgical prophylaxis
BY MOUTH
Adult: 400–500 mg, to be administered 2 hours before surgery, then 400–500 mg every 8 hours if required for up to 3 doses (in high-risk procedures)
Invasive intestinal amoebiasis | Extra-intestinal amoebiasis (including liver abscess)
BY MOUTH
Child 1–2 years: 200 mg 3 times a day for 5 days in intestinal infection (for 5–10 days in extra-intestinal infection)
Child 3–6 years: 200 mg 4 times a day for 5 days in intestinal infection (for 5–10 days in extra-intestinal infection)
Child 7–9 years: 400 mg 3 times a day for 5 days in intestinal infection (for 5–10 days in extra-intestinal infection)
Child 10–17 years: 800 mg 3 times a day for 5 days in intestinal infection (for 5–10 days in extra-intestinal infection)
Adult: 800 mg 3 times a day for 5 days in intestinal infection (for 5–10 days in extra-intestinal infection)
Urogenital trichomoniasis
BY MOUTH
Child 1–2 years: 50 mg 3 times a day for 7 days
Child 3–6 years: 100 mg twice daily for 7 days
Child 7–9 years: 100 mg 3 times a day for 7 days
Child 10–17 years: 200 mg 3 times a day for 7 days, alternatively, 400–500 mg twice daily for 5–7 days, alternatively, 2 g for 1 dose
Adult: 200 mg 3 times a day for 7 days, alternatively 400–500 mg twice daily for 5–7 days, alternatively 2 g for 1 dose
Giardiasis
BY MOUTH
Child 1–2 years: 500 mg once daily for 3 days
Child 3–6 years: 600–800 mg once daily for 3 days
Child 7–9 years: 1 g once daily for 3 days
Child 10–17 years: 2 g once daily for 3 days, alternatively 400 mg 3 times a day for 5 days, alternatively 500 mg twice daily for 7–10 days
Adult: 2 g once daily for 3 days, alternatively 400 mg 3 times a day for 5 days, alternatively 500 mg twice daily for 7–10 days

PRESCRIBING AND DISPENSING INFORMATION:

Metronidazole is well absorbed orally and the intravenous route is normally reserved for severe infections. Metronidazole by the rectal route is an effective alternative to the intravenous route when oral administration is not possible.

SIDE EFFECT:

Common or very common
With systemic use Dry mouth. myalgia. nausea. Oral disorders. taste altered. Vomiting With vaginal use Pelvic discomfort. vulvovaginal candidiasis vulvovaginal disorders
Uncommon
With systemic use Asthenia. headache. leucopenia (with long term or intensive therapy) With vaginal use Menstrual cycle irregularities. Vaginal haemorrhage
Rare or very rare
With systemic use Agranulocytosis. angioedema. Appetite decreased. ataxia. confusion. diarrhoea. dizziness. drowsiness. encephalopathy. epigastric pain. epileptiform seizure (with long term or intensive therapy). hallucination. hepatic disorders. meningitis aseptic. mucositis. neutropenia. optic neuropathy. pancreatitis. pancytopenia. peripheral neuropathy (with long term or intensive therapy). psychotic disorder. severe cutaneous adverse reactions (SCARs). skin reactions. thrombocytopenia. urine dark. vision disorders
Frequency not known
With systemic use Depressed mood. hearing impairment

INTERACTIONS:

Confessional state or acute psychosis with disulfiram. May potentiate anticoagulant effect of warfarin. May retain lithium serum levels increasing the risk to renal damage. Decreased serum concentration with phenobarbital or phenytoin. May increase serum concentrations of ciclosporin and busulfan. May reduce the renal clearance of 5-fluorouracil.

CAUTION:

With vaginal use Not recommended during menstruation. some systemic absorption may occur with vaginal gel

PREGNANCY:

With systemic use Manufacturer advises avoidance of high dose regimens; use only if potential benefit outweighs risk.

BREAST FEEDING:

With systemic use Significant amount in milk; manufacturer advises avoid large single doses though otherwise compatible; may give milk a bitter taste.

HEPATIC IMPAIRMENT:

With systemic use with caution in hepatic encephalopathy. Dose adjustments with systemic use in severe liver disease reduce total daily dose to one-third, and give once daily.

RENAL IMPAIRMENT:

void if possible or use with caution. Avoid in severe impairment. Dose adjustments the lowest effective dose should be used for the shortest possible duration. Monitoring In renal impairment monitor renal function; sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

CONTRA INDICATION:

Active gastro-intestinal bleeding. active gastro-intestinal ulceration. history of gastrointestinal bleeding related to previous NSAID therapy. history of gastro-intestinal perforation related to previous NSAID therapy. history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes). history of recurrent gastro-intestinal ulceration (two or more distinct episodes). inflammatory bowel disease. Severe heart failure

MONITORING REQUIREMENTS:

With systemic use Clinical and laboratory monitoring advised if treatment exceeds 10 days

OVERDOSAGE:

Symptoms: Nausea, vomiting, ataxia and slight disorientation.
Management: Symptomatic and supportive treatment.

STORAGE:

Bulk
Keep tightly closed in a cool dry place. Protect from light. Store below 30^0 C
Blister.
Keep the product in the outer package, in order to protect from light. Store below 30^0C

Keep all medicines away from children

Manufactured by
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.