Metronidazole
Film Coated Tablets

Composition:
Each film coated tablet (Metronidazole 250 mg) contains as active ingredient 250 mg Metronidazole.
Each tablet (Metronidazole 500 mg) contains as active ingredient 500 mg Metronidazole.

Exciptants:
Microcrystalline cellulose 25. Magnesium stearate. Dibasic calcium phosphate & Quinine yellow (in Metronidazole 250 mg F.C. Ts only)
Coat: Hydroxypropylmethylcellulose 6 cp, Polyethylene glycol 20000

Therapeutic indications:
Metronidazole is indicated for the treatment of symptomatic trichomoniasis, amebiasis, and giardiasis when the presence of the trophozoite has been confirmed by appropriate laboratory procedures (wet smears and/or cultures).

Asymptomatic trichomoniasis is indicated is for the treatment of asymptomatic females when the organism is associated with endocervicitis, cervicitis, or cervical erosion. Since there is insufficient data to recommend therapy for asymptomatic males, the treatment of the aerobic infection should be used in addition to Metronidazole.

Intra-abdominal infections:
Including peritonitis, intra-abdominal abscesses, and liver abscesses, caused by Bacteroides species including the B. fragilis group (B. fragilis, B. thetaiotaomicron, B. vulgatus), Clostridium species, Eubacterium species, Peptococcus niger, and Peptostreptococcus species.

Skin and skin structure infections:
Caused by Bacillus species including the B. fragilis group, Clostridium species, Eubacterium species, and Peptostreptococcus species.

Gynecologic infections:
Including endometritis, endomyometritis, tubo-ovarian abscesses, and postpartum vaginal infection, caused by Bacteroides species including the B. fragilis group, Clostridium species, Eubacterium species, and Peptostreptococcus species.

Bacterial Septicemia:
Caused by Bacteroides species including the B. fragilis group, and Clostridium species.

Bone and joint infections:
As adjunctive therapy, caused by Bacteroides species including the B. fragilis group, Clostridium species, Eubacterium species, and Peptostreptococcus species.

Central nervous system (CNS) infections:
Including meningitis and brain abscesses, caused by Bacteroides species including the B. fragilis group.

Endocarditis:
Caused by Bacteroides species including the B. fragilis group.

Lower respiratory tract infections:
Including pneumonia, empyema, and lung abscesses, caused by Bacteroides species including the B. fragilis group.

Metronidazole is indicated for the treatment of acute intestinal amebiasis (amebic dysentery) and amebic liver abscess.

Its use in the treatment of amebic liver abscess should be restricted to patients in whom the presence of the trophozoite has been confirmed by appropriate laboratory procedures.

The studies published in the literature do not make it possible to define the ideal protocol for surgical prophylaxis.

Bacteroides species including the B. fragilis group (B. fragilis, B. distasonis, B. ovatus, B. thetaiotaomicron, B. vulgatus), Clostridium species, Eubacterium species, Peptococcus niger, and Peptostreptococcus species.

Species with inconstant susceptibility:
Clostridium sp., Prevotella, Veillonella.

Antibacterial spectrum of Metronidazole concerns exclusively anaerobic pathogens: Bacteroides species including the B. fragilis group (B. fragilis, B. thetaiotaomicron, B. vulgatus), Clostridium species, Eubacterium species, Peptococcus niger, and Peptostreptococcus species.

In females (urethritis and vaginitis due to Trichomonas): single dose of 2 g or 500 mg/day by oral route for 10 days.

In males (urethritis due to Trichomonas): 2 g in a single dose, or 500 mg/day by oral route in 2 divided doses for 10 days.

For asymptomatic infections with known positive cultures, for prophylactic use, 250 mg twice daily for 7 days. The patient must be treated simultaneously.

Precautions:
General:
Patients with severe hepatic disease metabolize metronidazole slowly, with resultant increase in plasma half-life and volume of distribution. Use Metronidazole with extreme caution in patients with significant hepatic disease.

Patients who have been treated with metronidazole at high doses for cancer in Crohn’s disease patients who have been treated with metronidazole at high doses for extended periods of time. A cause and effect relationship has not been established.

Crohn’s disease patients are known to have an increased incidence of gastrointestinal and certain extraintestinal complications. It is possible that some patients will have been seen in gastrointestinal tract, particularly nausea reported by about 12% of patients, sometimes accompanied by headache, anorexia, and occasionally vomiting, diarrhea, erythematous distaste, and abdominal cramping.

Bacteroides species including the B. fragilis group, Clostridium species, Eubacterium species, Peptococcus niger, and Peptostreptococcus species.

Species with inconstant susceptibility:
Clostridium sp., Prevotella, Veillonella.

The susceptibility of the pathogens should be tested by an antibiotic.

The most serious adverse reactions reported in patients treated with Metronidazole have been convulsive seizures, encephalopathy, aseptic meningitis, optic and peripheral neuropathy. However, Metronidazole is generally well tolerated. Since peripheral neuropathy has been reported in some patients receiving prolonged administration of Metronidazole, serum creatinine levels and paired visual fields should be evaluated during therapy.

Overdosage:
There is no specific antidote for Metronidazole overdosage. In case of suspected massive overdose, a symptomatic and supportive treatment should be instituted.

To stop the drug and report immediately to their physicians if any neurologic symptoms occur.

- Busulfan:
- Vecuronium
- Chloral hydrate
- Alcohol:
- The alcoholic metabolite which has a bactericidal activity on the anaerobic pathogens on average
- The plasma half-life is 8 to10 hours.
- Bioavailability:

Dosage & method of administration:

Bacteroides species including the B. fragilis group, Clostridium species, Eubacterium species, Peptococcus niger, and Peptostreptococcus species.

Species with inconstant susceptibility:
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Pharmacological properties:

Metronidazole potentiates the action of oral anticoagulants by decreasing oral anticoagulant hepatic catabolism, prothrombin level should be monitored for 8 days after discontinuation. It is therefore not recommended for the use of oral anticoagulants.

Because of the potentiation of oral anticoagulants effect and hemorrhagic risk (decrease in the oral anti-coagulant hepatic catabolism), prothrombin level should be monitored closely and additional anticoagulant dosage must be adjusted during Metronidazole treatment and 8 days after discontinuation.

- Metronidazole 250 mg is rapidly absorbed following oral administration; at least 80% is absorbed in less than one hour.
- The plasma protein binding is less than 20%.
- The volume of distribution is 40 L (i.e. 6.65 L/kg).
- Diffusion is rapid and tissue concentrations are similar to serum concentrations, in lungs, kidneys, liver, skin, bile, 2% fat, saliva, all fluid and vaginal secretions.
- The acid metabolite is low with a bactericidal activity of 5% of the ingested dose.

- Hepatic and biliary concentrations are high. Colon and fecal concentrations are low.

- Storage:
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

-呈rentations:
- Cardax containing 10 strips/Aluminum(PVC)/X 10 Tablets and inner pamphlet.

Produced by: Alexandria Co. for Pharmaceuticals & Chemicals Industries- Alexandria - A.R.E.

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