



Ramazol[®]

Metronidazole

DESCRIPTION: Ramazol (metronidazole) is an anti-protozoal agent with anti-microbial activity against anaerobes.

PROPERTIES: Ramazol acts effectively on trichomoniasis, it is rapidly absorbed orally and excreted unchanged in the urine.

INDICATIONS: Ramazol is indicated for the treatment and prevention of the following diseases:

- Acute intestinal amebiasis and Extra-intestinal amebiasis including amoebic liver abscess caused by *Entamoeba histolytica*.
- Giardiasis caused by *Giardia Lamblia*.
- Infections caused by bacteroides species including *B. Fragilis* and *Clostridium* species, *Eubacterium* species *Peptococcus* species and *Peptostreptococcus* species including (Brain abscess, Meningitis, bone and joint infection, endocarditis, intra-abdominal infections, pelvic infections, pen-operative infections, pneumonia, septicemia, skin and soft tissue infections, colitis, *H. Pylon* associated gastritis and duodenal ulcer, and dental infections).

DOSAGE AND ADMINISTRATION:

Instruction for the patients:

Metronidazole may be taken with meal or a snack to lessen gastro intestinal irritation. In the treatment of trichomoniasis the other partner should received **Ramazol** as concurrent therapy.

Adults dosage: In amebiasis, dysentery and balantidiasis, 400 - 800 mg three times daily for 5 to 10 days.

Children dosage: from 1 - 3 years (100 - 200 mg three times daily), from 3 - 7 years

(150 - 300 mg three times daily), from 7 - 10 years (200 - 400 mg three times daily) for 5 - 10 days for all ages; alternatively 35 - 50 mg per kg body weight daily in divided doses has been suggested. In giardiasis, the usual adult dose of metronidazole is 2 grams daily as single dose for 3 successive days.

Children dosage is proportional as for amebiasis above, an alternative schedule is 250 mg three times daily for 5 day for adults; and 15 mg per kg body weight daily in divided doses for children. In case of acute trichomoniasis 2 gram daily as single dose or 200 - 250 mg three times daily for seven days in case of chronic trichomoniasis. The course should be repeated after one week.

- For most anaerobic bacterial infections; an initial dose of 800 mg followed by 400 mg every 8 hours for 7 days. Children may be given 7.5 mg per kg every 8 hours.

- Acute dental infections: 250 mg three times daily for 3 - 7 days.

- Ulcerative colitis and duodenal ulcer: **Adult dose:** 500 mg twice a day.

Children dose: 15 mg / kg / day divided into two doses.

(RESTRICTIONS ON USE)

CONTRAINDICATIONS: Hypersensitivity to metronidazole or any component of the tablet or any derivative of imidazole group.

SAFETY MEASURES AND WARNINGS:

- Alcoholic beverages should be avoided during treatment with metronidazole.
- Patients with severe hepatic diseases should receive lower doses.
- Metronidazole should be used with caution in patients with epilepsy, or history of central nervous system disorders.
- Caution should be taken in patients with impaired hepatic or renal function and reduction in the dose may be required.

USE DURING PREGNANCY AND LACTATION:

Metronidazole should not be used at the first trimester of pregnancy.

- Metronidazole should be used with caution for pregnant women (at least 6 months) and during lactation.

DRUG INTERACTIONS: Patients must consider the effect of anticoagulants particularly warfarin and coumatin.

SIDE EFFECT: Gastrointestinal tract disturbances such as : nausea, metallic taste, vomiting, diarrhea, abdominal pain.

- CNS disturbances such as: dizziness, headache.

- Skin reactions: Skin rashes, urticaria, pruritis.

Pharmacologically active constituents:

COMPOSITION AND PRESENTATIONS:

Ramazol 250 Tablets: each tablet contains 250 mg of metronidazole. Blister Packs of 30/20 Tablets

Ramazol 500 Tablets: each tablet contains 500 mg of metronidazole. Blister Packs of 30/20 Tablets.

Ramazol 200 suspension: each 5 ml contains 200 mg of metronidazole benzoate eq. to 125 mg metronidazole base (bottle of 100ml).

STORAGE AND DISPOSAL: The shelf life of Ramazol is 3 years if stored at a temperature between 15 - 30°C in the original undamaged pack.

Discard the medicament after the expiry date.

More information: The leaflet information is limited. For further information, please contact your doctor or pharmacist. Ramazol is product and trade-mark of RAM PHARMA Aceutical, Amman - Jordan.

Some presentations may not be available in some countries.

Hospital packs of different sizes are available.

This is a Medicament :

- Keep all medicaments out of reach of children.
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment before consulting your doctor.
- Do not repeat the same prescription without consulting your doctor.