Metrolag®

Metronidazole

Composition

Tablets containing 250 mg or 500 mg metronidazole.
Vaginal tablets containing 500 mg metronidazole
Suppositories containing 500 mg or 1 g metronidazole
Oral Suspension containing metronidazole benzoate equivalent to 25 mg metronidazole per ml.
Solution for intravenous infusion containing 5 mg metronidazole per ml.

Properties

Metronidazole, a synthetic drug, is considered the drug of choice for treatment of infections due to various protozoa such as: amoeba, giardia (lamblia) and Trichomonas vaginalis. It is therefore particularly indicated for treatment of intestinal and hepatic amoebiasis, and forms of urethritis and vaginitis caused by Trichomonas vaginalis; in the latter case the simultaneous treatment of patient and partner is strongly recommended.
Metronidazole is also very active against a wide range of obligate anaerobic bacteria such as Fusobacterium Clostridium and various strains of Bacteroides. It has however no effect on facultative aerobic bacteria and its use therefore does not affect the normal population of these organisms in man.
Cases of resistance to metronidazole are rather rare. Metronidazole is absorbed rapidly and nearly completely from the gastro-intestinal tract. The maximum concentrations in the blood are achieved about four hours after administration. About half the dose administered is metabolised and 50% is rapidly eliminated via the kidneys. The drug passes the placenta and is found in the breast milk in concentrations corresponding to those in the mother's serum.

Indications

Trichomoniasis. Intestinal and hepatic amoebiasis. Giardiasis (lambliasis). Acute ulcerative gengivitis (Vincent's gengivitis). Prevention and treatment of infections due to anaerobic bacteria. Pre- and post-operative prophylaxis in gynecological and gastro-intestinal surgery.

Dosage

Trichomoniasis single dosis: 2 g in a single dose or 250-500 mg twice a day for 6 days. The treatment for women is mixed: systemic treatment (oral) associated with local treatment (one vaginal tablet each evening for 6 days). The patient and partner should be treated simultaneously.

Acute intestinal amoebiasis:

ADULTS: 2.0 - 2.5 g in a single dose for 2-3 days or 500 mg three times daily for 5 days.
CHILDREN: half the adult dose.
INFANTS: 50 mg/kg body-weight daily.

Giardiasis:

ADULTS : 2 g in a single dose for 3 days or 500 mg twice daily for 5-10 days.
CHILDREN: 250 mg once daily for 10 days.
INFANTS: 25 mg/kg body-weight for 10 days.

Anaerobic infections:

1) Treatment:

Oral: Adults and children over 12 years old: an initial dose of 30 mg/kg body-weight followed by a dose of 7 mg/kg every 8 hours.
Rectal: The adult usual dose is 1 g, for children from 5 to 12 years old is 500 mg, and for children below 5 years old is 7 mg/kg body-weight every 8 hours.
Intravenous: Adults and children over 12 years old: 0.5 g (100 ml) every 8 hours.
Children under 12 years old: 7 mg/kg body-weight every 8 hours.
Recommended rate of infusion: 5 ml per minute.
In general, treatment should not be given for more than 7 days.

2) Prevention:

a) Pre-operative : (particularly before hysterectomy and surgery of the colon):
Adults and children over 12 years old: one day prior to surgery 1 g is administered orally followed by 250 mg orally every 8 hours up to preoperative fast.
b) Operative and post-operative periods: 0.5 g - 1 g by intravenous infusion returning as quickly as possible to oral administration 250 mg 3 times daily.
Children under 12 years old: 7 mg/kg body-weight every 8 hours.
c) Acute surgery: (appendicectomy, gastro-intestinal perforation): Adults and children over 12 years old: 0.5 g -1 g intravenously immediately before, during and after surgery followed by the same dose every 8 hours until oral medication can be given 250 mg X 3 times daily.
Children under 12 years old: 7 mg/kg body-weight every 8 hours.
In general, preventive treatment should not be given for more than 3-7 days.

Side effects

Mild gastro-intestinal disorders such as nausea, vomiting, diarrhea may appear but such effects are temporary and rapidly disappear. Moderate leukopenia may occur during treatment; (during long-term treatment regular blood formula controls are recommended).

Overdosage

Single oral doses of up to 15 g have been reported to cause nausea, vomiting and ataxia during the first 12 hours, but otherwise no symptoms. There is no specific antidote for metronidazole overdosage, therefore management of the patient should consist of symptomatic and supportive therapy.

Drug interactions and precautions

- use of barbiturates along with metronidazole should be avoided, as it appears to decrease the serum concentration of the drug.
- cimetidine should not be used along with metronidazole as cimetidine being an enzyme inhibitor, can decrease the hepatic metabolism of metronidazole, resulting in its delayed elimination and thereby an increase in the serum concentrations.
- concomitant intake of metronidazole along with disulfiram should be avoided as it may cause acute confusional state resulting in psychotic reactions.
- metronidazole may potentiate the activity of oral anticoagulants and hence combination therapy should be avoided.
- intake of alcoholic beverages should be avoided throughout the treatment with metronidazole as it may induce disulfiram-like reaction and may also result in vomiting and stomach cramps.
- when patients stabilised on a relatively high dose of lithium are given metronidazole, signs of lithium toxicity has been reported in several cases and hence should be avoided.
- metabolism of phenytoin is inhibited resulting in increased plasma phenytoin concentration when used along with metronidazole.

Ask your pharmacist if you are taking of these medications together.

Contra-indications

- Anomalies of the blood formula.
- Central nervous system disorders.
- Metronidazole is contra-indicated during the first three months of pregnancy; during the following months oral administration should be limited to those cases in which local application has proved inadequate.

Pregnancy and lactation

- as metronidazole crosses the placenta, the drug is contra-indicated in the first trimester of pregnancy.
  During the following months, oral administration should be limited to those cases in which local application has been proved inadequate.
- administration of metronidazole should be avoided in breast feeding mothers as the drug is found in breast milk in concentrations similar to those in maternal blood plasma.

Storage

Store at room temperature (15-25°C) in the original packaging.
Keep out of the reach of children. The preparation is stable up to expiry date (EXP) shown on commercial pack.

Packing

Tablets: 250 mg: 20's, 100's; 500 mg: 4's, 8's, 24's, 100's
Vaginal Tablets: 10's
Suppositories: 50's
Oral Suspension: Bottle of 60 ml, 100 ml
Infusion Solution: Flexible bags of 100 ml (500 mg / 100 ml).

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children!

Council Of Arab Health Ministers Union of Arab Pharmacists

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Lagap

Lagap SA, 6943 Vezia / Switzerland