

METROLAG®

COMPOSITION

Active ingredient
Metronidazole BP2.5 g
(as Metronidazole benzoate : 4 g)

Excipients

Tylose, avicel, glycerine, tween 80, ethanol, sodium saccharine, methyl paraben, propyl paraben, sorbitol, orange flavor, demineralized water.

PHARMACEUTICAL FORM

Oral suspension, 100 mL vial

PHARMACO-THERAPEUTIC CLASS

Antiparasitic, antiinfective

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.

SIDE EFFECTS

Mild gastro-intestinal disorders such as nausea, vomiting, diarrhea, abdominal cramps, metallic taste in the mouth, loss of appetite 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).

Exceptionally, allergic reactions (itching, flushing, urticaria, fever, angioedema, anaphylactic shock, peripheral and central nervous system disorders, reversible cases of pancreatitis.

At high dosage and/or during prolonged treatment : hematological disorders, in particular leucopenia, peripheral sensory neuropathies, decreasing after discontinuation of treatment.

PRECAUTIONS

Oral treatment with metronidazole should be avoided during breast-feeding.

Throughout treatment patients should abstain from drinking alcoholic beverages which could give rise to vomiting and to stomach cramps.

Interactions with other drugs may occur, particularly with Disulfiram, oral anticoagulants (warfarin type), lithium and cyclosporin.

CONTRA - INDICATIONS

Anomalies of the blood formula.

Central nervous system disorders.

Metrolag 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.

INDICATIONS

Trichomoniasis.

Intestinal and hepatic amoebiasis.

Giardiasis (lambliaosis).

Acute ulcerative gingivitis (Vincent's gingivitis).

Prevention and treatment of infections due to anaerobic bacteria.

Pre- and post - operative prophylaxis in gynecological and gastro-intestinal surgery.

DOSAGE

Amoebiasis :

Children : 30 to 40 mg/Kg per day.

The daily dose should be taken as three divided doses preferably during meals.

The treatment generally lasts 7 consecutive days.

Giardiasis :

Children :

- From 2 to 5 years old : 250 mg (10 mL) per day.

- From 5 to 10 years old : 375 mg (15 mL) per day.

- From 10 to 15 years old : 500 mg (20 mL) per day.

The daily dose should be taken as a single dose or 2 divided doses, preferably during meals for 5 consecutive days.

Anaerobic infections :

Children : 20 to 30 mg/Kg per day.

METHOD OF ADMINISTRATION

Oral route. Shake bottle before use.

CONSERVATION

All medicines should be kept out of children's reach.

Do not use when expired (expiry date on the box).

Keep in a dry cool place at room temperature under 25°C.

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