



LEAFLET

METAGO-250

Metronidazole Tablets BP 250 mg

COMPOSITION

Tablet : Each uncoated tablet contains : Metronidazole BP 250 mg

THERAPEUTIC CLASSIFICATION

ANTIPROTOZOLAS (OTHER THAN ANTIMALARIALS)

PHARMACOLOGICAL ACTIONS

It is active against a wide range of pathogenic organisms notably species Bacteroides, fusobacteria, Eubacteria, anaerobic cocci and Trichomonas vaginalis. Its mechanism of action is thought to involve interference with DNA by metabolite in which the ritro group of Metronidazole has been reduced.

Metronidazole rapidly and almost completely absorbed leading to peak plasma levels after 20 mins-3 hrs. The elimination half-life of Metronidazole is 7- 8 hrs.

INDICATIONS

- The prevention of postoperative Infections due to anaerobic bacteria like streptococci.
- The treatment of septicemia, bacteraemia, peritonitis, brain abscess, necrotizing pneumonia, pelvic abscess pelvic cellulites and postoperative wound infections.
- Urogenital trichomoniasis in the female (trichomonal vaginitis) and in the male.
- Non-specific vaginitis.
- All forms of amoebiasis (intestinal and extraintestinal disease).
- Giardiasis.
- Acute ulcerative gingivitis.

CONTRA-INDICATIONS

This drug is contraindicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives. Metronidazole is also contraindicated in patients with trichomoniasis during the first trimester of pregnancy.

WARNINGS

Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paraesthesia of an extremity have been reported in patients treated with Metronidazole. The appearance of abnormal neurologic signs demands the prompt discontinuation of Metronidazole treatment. It should be administered with caution to patients with central nervous systems diseases.

PRECAUTIONS

It should be used with caution in patients with hepatic diseases, since delayed metabolism of Metronidazole results in accumulation of Metronidazole and its metabolites in the plasma. Alcoholic beverages should be avoided while taking Metronidazole and for atleast one day after treatment. Metronidazole is secreted in breast milk in concentrations similar to those found in the plasma.



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

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1.5.3 Patient information leaflet (PIL)

ADVERSE REACTIONS

Unpleasant taste in the mouth, furry tongue, nausea, vomiting, gastrointestinal disturbance, urticaria and angiodema occur occasionally. Anaphylaxis may occur rarely. Drowsiness, dizziness, headache, ataxia, skin rashes, pruritus, darkening of the urine (due to Metronidazole metabolite) have been reported but very rarely. During intensive and/or prolonged Metronidazole therapy, a few instances of peripheral neuropathy or transient epileptiform seizures have been reported.

DOSAGES AND ADMINISTRATION

In amoebiasis: Metronidazole is given orally in dose of 400 to 800 mg three times a day daily for 5 to 10 days. Children aged between 1 to 3 years may be given one quarter, those aged between 3 to 7 years, one third, and those between 7 to 10 years one half the adults dose.

In giardiasis : The usual oral dose is 250 mg three times daily for 5 to 7 days or adults; or 15 mg/kg daily in divided doses for children.

In trichomoniasis : Metronidazole is given daily as a single 2 gm-dose as a 7 days course of 200 or 250 mg three times daily 400 mg twice daily. Sexual partners should be treated concomitantly.

Anaerobic bacterial infections: Metronidazole is given orally in an initial dose of 800 mg followed by 400 mg every 8 hours, usually for 7 days or as directed by the physician.

STORAGE

Store under normal storage conditions (15°C to 30°C).

Protect from light.

Keep all medicines away from reach of children.

PRESENTATION

Blister pack of 10 X 10 Tablets.

Bulk pack of 1000 Tablets.

Manufactured in India by



AGOG PHARMA LTD.

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