

Mecozaal Plus (Vaginal Suppositories)



Chemical Composition: Each vaginal Suppository contains Metronidazole 500 mg, Miconazole Nitrate 100mg.

Excipients: Hydrogenated vegetable oil, Aerosil.

PHARMACODYNAMICS:

This product contains miconazole for antifungal, metronidazole for antibacterial and antitrichomonal effects. Miconazole nitrate which is an antifungal has a wide spectrum of activity and is particularly effective against pathogen fungi including *Candida albicans*. In addition, miconazole nitrate is effective against Gram (+) bacteria. Metronidazole is an antibacterial and antiprotozoal agent that is effective against *Gardnerella vaginalis* and against anaerobic bacteria including anaerobic streptococci and *Trichomonas vaginalis*.

PHARMACOKINETICS:

Absorption of miconazole nitrate through the intravaginal route is very low (approximately 1.4% of dose). Bioavailability of metronidazole by this route is 20% compared to the oral route. Miconazole nitrate cannot be detected in plasma after vaginal application of the suppository. Steady state level of metronidazole in plasma reaches 1.6 – 7.2 µg/ml. Metronidazole is metabolized in the liver. The hydroxyl-metabolite is effective. The half-life of metronidazole is 6- 11 hours. Approximately 20% of the dose is excreted unchanged in urine.

INDICATIONS:

Metronidazole + Miconazole nitrate vaginal suppository is used for local treatment of vaginalis infection with the involvement of certain fungi (eg *Candida albicans*), some bacteria and other pathogenic organisms (*Trichomonas vaginalis*).

CONTRAINDICATIONS:

Metronidazole + Miconazole nitrate should not be used in the following cases:

- Hypersensitivity to any of the ingredients of the suppository.
- Pregnancy (particularly in the first 3 months).
- Severe problems with liver (liver function disorders including metabolic disease called "porphyria").
- Diseases of the nervous system.
- Disturbances in the production of blood.

WARNINGS / PRECAUTIONS:

Alcohol should not be taken during the therapy and for at least 24-48 hours after the end of course of treatment because of the possibility of increased alcohol incompatibility.

The suppository should not be used together with the contraceptive diaphragms and condoms since the ovule base may affect the rubber, which may possibly break.

Pregnancy and Lactation:

After the first three months of pregnancy, Metronidazole + Miconazole nitrate suppository can be used when considered essential by the doctor, but must be used under observation.

Breastfeeding is not allowed while using Metronidazole + Miconazole nitrate, since active ingredients pass into the milk. Breastfeeding may be started again 24-48 hours after the treatment is finished.

SIDE EFFECTS:

Vaginal Disorders: Vaginal irritation (burning, itching). Owing to the inflammation of the vaginal mucosa in vaginitis, vaginal irritation can be seen after the administration of the first suppository or towards the 3rd day of the treatment. These complaints disappear quickly when the treatment continues. If there is severe irritation, the physician should be informed because it may be necessary to stop the treatment.

Gastrointestinal Disorders: Abdominal pain or cramps, metallic taste, constipation, dry mouth, seldom diarrhea, lack of appetite, vomiting, nausea.

Nervous System Disorders: Headache, ataxia, dizziness, mental changes, peripheral neuropathy after overdose or long period of usage, cramps.

Skin Disorders: Rash.

Blood Disorders: Decreased white blood cells.

DRUG INTERACTIONS:

Due to absorption of active ingredients of Metronidazole + Miconazole nitrate, interactions may occur if the preparation with alcohol is used (Metronidazole + Miconazole nitrate may lead to an increased alcohol incompatibility) or any of the following drugs:

- Drugs that make your blood thinner (oral anti-coagulants).
- Anti-epileptics (phenytoin, phenobarbital) –A drug reducing the acid in your stomach (cimetidine).
- A drug for the treatment of alcoholism (disulfiram).
- A drug against psychosis and depression (lithium).
- Anti-allergic medicines (astemizole and terfenadine).

Laboratory tests may change while using Metronidazole + Miconazole:

interference with blood levels of liver enzymes, glucose (hexokinase method), theophylline, and procainamide have been observed.

DOSAGE & ADMINISTRATION:

Do not use without consulting a physician. Unless your doctor advises otherwise, insert 1 vaginal ovule at night and 1 vaginal ovule in the morning for 7 days. In recurrent cases, or when vaginitis has resisted other treatments, 1 vaginal ovule should be inserted high into the vagina at night and in the morning for 14 days. The ovule should be inserted high into the vagina.

Elderly (over 65 years): Dosage as for younger adults.

Children: Not recommended for children.

OVERDOSAGE AND TREATMENT:

There is no human experience with overdose of Metronidazole + Miconazole nitrate suppository. Metronidazole could be absorbed in sufficient amounts to produce effects in the body. If large quantities of the product are accidentally taken, an appropriate method of emptying the stomach may be considered necessary. Symptoms of Metronidazole overdose are nausea, vomiting, abdominal pain, diarrhea, itching, metallic taste, movement disorders (ataxia), vertigo, unusual sensations on the skin (paresthesia), cramps, decrease of white blood cells, and darkening of urine. Symptoms of Miconazole nitrate overdose are nausea, vomiting, sore throat and mouth, decrease appetite, headache and diarrhea.

Storage conditions: Store at room temperature, below 25°C.

Package: Box contains 2 plastic blisters, each blister contains 7 Suppositories

★ THIS IS A MEDICATION ★

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

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