

SUMMARY OF PRODUCT CHARACTERISTICS

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Trimic

(Metronidazole & Miconazole Nitrate Vaginal Suppositories)

NAME OF THE MEDICINAL PRODUCT

TRIMIC

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vaginal suppository contains

Metronidazole BP500 mg

Miconazole Nitrate BP..... 100 mg

Hard Fatq.s

For full list of excipients refer 6.1

PHARMACEUTICAL FORM

Vaginal Suppositories

White to off white opaque bullet shaped suppositories.

CLINICAL PARTICULARS

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMICS

Trimic (Metronidazole, Miconazole Nitrate vaginal suppository) contains miconazole for antifungal and 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 *Gardenella vaginalis* and against anaerobic bacterial including anaerobic streptococci and *Trichomonas vaginalis*.

PHARMACOKINETICS

Absorption of miconazole nitrate through the intravaginal route is very low. Bioavailability of metronidazole by this route is 20 percent compared to the oral route. Miconazole nitrate cannot be detected in plasma after vaginal application of Trimic. 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 percent of the dose is excreted unchanged in urine.

INDICATIONS

Trimic (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*). Your doctor needs to decide whether Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) is suitable for the treatment of your condition.

CONTRAINDICATIONS

You should not use Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) if:

- You suffer from hypersensitivity to any of the ingredients of the suppository
- You are pregnant (particularly in the first 3 months)

Your doctor needs to carefully evaluate whether you may use Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) if you suffer from:

- Severe problems with your liver (liver function disorders including metabolic disease called “porphyria”)
- Diseases of the nervous system
- Disturbances in the production of blood (hematopoiesis)

WARNINGS /PRECAUTIONS

You must not take alcohol 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. You must not use the suppository together with the contraceptive diaphragms and condoms since the vaginal suppository base may affect the rubber, which may possibly break.

PREGNANCY AND LACTATION

After the first three months of pregnancy, Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) can be used when considered essential by your doctor, but must be used under observation. You must not breastfeed your baby while using Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories), since active ingredients pass into the milk. You may start breast feeding again after 24-48 hours after the treatment is finished.

SIDE EFFECTS / ADVERSE RECACTIONS

Medical events judged to be common, uncommon and rare are listed below.

Vaginal disorders

Vaginal irritation (burning, itching) owing to inflammation of vaginal mucosa in vaginitis, vaginal irritation can be seen after the administration of the first ovule or towards the third day of treatment. These complaints disappear quickly when the treatment continues. If there is severe irritation, contact your doctor because it may be necessary to stop the treatment.

Stomach and intestinal disorders

Abdominal or cramp, Metallic taste, constipation, dry mouth, seldom diarrhea, lack of appetite, vomiting and nausea.

Nervous system disorders

Headache, movement disorders (ataxia), dizziness, mental changes, disorders of the nerves (peripheral neuropathy) after overdose or long period of usage, cramps.

Skin disorders

Rash

Blood disorders

Decrease of white blood cells

INFORM YOUR PHYSICIAN WHENEVER AN UNEXPECTED EFFECT IS OBSERVED

DRUG INTERACTIONS

Due to absorption of active ingredients of Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) interactions may occur if you used the preparation with alcohol Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories) may lead to an increased alcohol incompatibility) or with any of the following drugs (inform your doctor if you take them):

- 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 you use Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories):

Interference with blood levels of liver enzymes, glucose (hexokinase method), theophylline, and procainamide have been observed. If blood tests are made, remind your doctor that you use Trimic.

DOSAGE AND ADMINISTRATION

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

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

Children: Not recommended for children.

Not recommended for virgins.

Not to be swallowed or applied by other routes.

OVERDOSAGE AND TREATMENT

There is no human experience with overdose of Trimic (Metronidazole & Miconazole Nitrate Vaginal Suppositories). If large quantities of the product are accidentally taken, an appropriate method of emptying your 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.

PHARMACEUTICAL PARTICULARS

List of excipients

Hard Fat

Incompatibilities

There is not any known incompatibility.

Shelf life

24 months

Special precautions for storage

Store in dry place, below 30°C.

Protect from light.

Keep the product in its original package.

Keep out of reach and sight of children.

Nature and contents of container

Two blisters of 7 Vaginal Suppositories each are packed in a carton along with an insert.

Instructions for use and handling and disposal.

Unused products or waste materials should be disposed according to local related guidelines.

MANUFACTURED BY:

BLISS GVS PHARMA LTD., 102, Hyde Park, Saki Vihar Road, Andheri (E), Mumbai – 400072,
India.

MARKETING AUTHORIZATION NUMBER (S)

NA

DATE OF REVISION OF THE TEXT

March 2018