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What is Trimic used for

TRIMIC (Metronidazole & Miconazole Nitrate Vaginal Suppositories) should be used in the treatment of vaginal candidiasis, bacterial and trichomonal vaginitis, or vaginitis due to mixed infections.

Trimic is vaginal suppository which consist of 500 mg of Metronidazole and 100 mg of Miconazole Nitrate. It is used for local treatment of vaginalis infection with the involvement of certain fungi (e.g. *Candida albicans*), some bacteria and other pathogenic organisms (*Trichomonas vaginalis*).

Trichomoniasis is a very common sexually transmitted disease (STD) that is caused by infection with a protozoan parasite called *Trichomonas vaginalis*. About 70% of infected people do not have any signs or symptoms. When trichomoniasis does cause symptoms, they can range from mild irritation to severe inflammation.

Candidal vaginitis is vaginal infection with *Candida sp*, usually *C. albicans*. Most fungal vaginitis is caused by *C. albicans*, which colonizes 15 to 20% of nonpregnant and 20 to 40% of pregnant women.

Bacterial vaginosis, which results from overgrowth of one of several organisms normally present in vagina. Bacterial vaginosis is the most common vaginal infection in women ages 15-44.

How Trimic works

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*.

Before you use Trimic

-When you must not use it

Do not use Trimic if you are allergic (hypersensitive) to metronidazole, miconazole nitrate or any of the other ingredients of Trimic.

-Before you start to use it

Take special care with Trimic and check with your doctor or pharmacist before using your medicine if:

- You have or have ever had a liver problem
- You are having kidney dialysis
- You have a disease of the nervous system
- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is better not to use Trimic if you are breast-feeding. This is because small amounts may pass into the mother's milk.

-Taking other medications

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.

How to use Trimic

-How much to use

Do not use without consulting a physician.

If it is not advised otherwise by a physician, 1 pessary should be inserted high into the vagina at night for 14 days or 1 pessary at night and 1 pessary in the morning for 7 days. In recurrent cases, or when the vaginitis has been resistant to other treatments, 1 pessary should be inserted high into the vagina at night and in the morning for 14 days.

For elderly patients (over 65 years): As for younger adults.

Children: Not recommended for children.

Not to be swallowed or not to be applied by other routes.

-When to use it

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.

-How long to use it

The length of your treatment will depend on the type of infection you have and how bad it is.

-If you forget to use it

Do not use a double dose to make up for a forgotten dose.

-If you use too much (overdose)

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 and diarrhea.

While you are using it

-Things you must do

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)

-Things you must not do

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.

-Things to be careful of

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)

Side effects

Like all medicine, Trimic also cause adverse effects. The adverse effects may vary from patient to patient. The commonly reported adverse effects are vaginal irritation (burning, itching), abdominal pain or cramp, metallic taste, constipation, dry mouth, seldom diarrhea, lack of appetite, vomiting, nausea, headache, movement disorders, dizziness, mental changes. However, you may experience other adverse effects which are not listed above. If you cannot tolerate the adverse effect talk to your doctor or pharmacist and discontinue the therapy.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.npra.gov.my (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Trimic

- Storage

Store at temperature not exceeding 30°C. Protect from light. Store in the original package in order to protect them from light. Keep your suppositories in a safe place out of the reach and sight of children.

-Disposal

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

Product Description

-What it looks like

White to off white opaque bullet shaped suppositories.

-Ingredients

- Active ingredient(s)
Metronidazole, Miconazole Nitrate
- Inactive ingredient(s) Hard Fat

-MAL number –

Manufactured by:

Bliss GVS Pharma Ltd.,

Plot No. 11, Survey No. 38/1, Dewan Udyog Nagar, Aliyali Village, Taluka Palghar, Thane 401 404, Maharashtra State, India.

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd., 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, Malaysia.

Date of revision -

12.06.2018

Serial Number

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