PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Metrogyl®
Tablets

The active ingredient and its quantity:
Each tablet contains:
Metronidazole 250 mg

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of infections caused by amoebae, trichomonas, anaerobic bacteria, or bacteria susceptible to metronidazole.
The medicine contains an active ingredient called metronidazole that belongs to a group of medicines called antibiotics.
It works by killing bacteria and parasites that cause infection in your body.
In certain cases, your partner will require simultaneous medicinal treatment, even if he/she does not experience any symptoms.
When the medicine is prescribed to treat trichomonas, it is recommended that your partner use a condom when having sex during the course of treatment – please consult a doctor.

Therapeutic group:
An imidazole antimicrobial preparation.

2. BEFORE USING THE MEDICINE:

☒ Do not use the preparation if:
- Do not use the medicine during the first trimester of pregnancy.
- Do not use this medicine if there is a known sensitivity to metronidazole, nitroimidazole (e.g., tinidazole) or to any of the ingredients of the medicine (see section 6).
- Do not consume alcohol during treatment or for 48 hours after completing the treatment.

Special warnings regarding use of the medicine

❗ Before treatment with Metrogyl®, tell the doctor if:
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine
- If you are suffering, or have suffered in the past, from impaired function of the liver
- If you are having kidney dialysis (see section 3 – People undergoing dialysis)
- If you have a disease of the nervous system

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking or plan to take:
- Anticoagulants (warfarin)
- Disulfiram (for alcoholism)
- Cimetidine (for ulcer)
- 5-fluorouracil (anti-cancer medicines)
- Phenytoin or phenobarbital (anti-epileptics)
- Lithium (for mental illnesses)
- Cyclosporine (to prevent graft rejection)
- Busulfan for leukemia (for cancer of the blood cells)

❗ Use of the medicine and food:
Take the medicine with or immediately after completing a meal.

❗ Use of the medicine and alcohol consumption:
Do not drink alcoholic beverages during the course of treatment with this medicine and for 48 hours after completing the treatment.
Drinking alcohol while taking Metrogyl® can cause unpleasant side effects, such as nausea, vomiting, abdominal pains, hot flashes, rapid or irregular heart rate and headache.

❗ Pregnancy and breastfeeding:
Inform the doctor before starting treatment with Metrogyl® if you are pregnant, are planning to become pregnant, or think you are pregnant, or if you are breastfeeding. Do not take Metrogyl® during pregnancy or when breastfeeding unless there is an absolute need for treatment.
It is recommended not to breastfeed during treatment with Metrogyl®, since the medicine may pass into breast milk.

❗ Driving and use of machinery:
Taking Metrogyl® may cause sleepiness, dizziness, confusion, hallucinations (seeing or hearing things that do not exist), convulsions or temporary vision problems (such as blurred vision or double vision).
If these effects occur, do not drive or operate machinery or tools.

❗ Important information regarding some of the ingredients of the medicine:
Metrogyl® contains sodium (see section 6).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
The dosage and treatment regimen will be determined by the doctor only. It is important to complete the full course of treatment. The dosage and duration of treatment depend on the type of ailment.
Swallow the tablet with water, after or with a meal.
People undergoing dialysis – dialysis removes Metrogyl® from the blood. If you are undergoing dialysis, take Metrogyl® after the dialysis treatment.
People with liver problems – the doctor may instruct you to use a lower dosage than usual or less often than usual.
Do not exceed the recommended dose.

Tests and follow-up
- During prolonged treatment (more than 10 days) with this medicine, blood tests should be performed.
- If the medicine is being used to treat amoebae in the digestive system, check that the infection has disappeared at the end of the treatment by performing stool tests.

If you accidentally took a higher dosage, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine, take a dose as soon as you remember. But if it is almost time for the next dose, skip this dose and take the next dose at the usual time and consult a doctor. Do not take a double dose to compensate for a missed dose.

How can you contribute to the success of the treatment?
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health condition, do not discontinue treatment with this medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Metrogyl® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to a doctor or hospital immediately if:
- if you are suffering from an allergic reaction that includes: swelling of the hands, legs, ankles, face, lips or throat, that can cause difficulty swallowing or breathing. An itchy rash may also appear.
- brain injury (encephalopathy): a serious but very rare effect. The symptoms of this effect vary, but you may suffer from fever, stiff neck, headache, hallucinations (seeing or hearing things that do not exist). You may suffer from difficulty in moving the arms and legs, speech problems or a feeling of confusion.

Refer to a doctor immediately if you notice the following side effects:
- yellowing of the skin and eyes. Can arise from liver problems (jaundice).
- unexpected infection, mouth ulcers, bruises, bleeding gums or severe fatigue. Can arise from blood problems.
- severe abdominal pain, which can reach through to the back (may be an indication of pancreatitis).

Refer to a doctor or pharmacist if you notice the following side effects:
Side effects that appear very rarely (occur in less than 1 in 10,000 people):
- convulsions (fits).
- mental problems, such as a sensation of confusion and hallucinations (seeing or hearing things that do not exist).
- vision problems, such as blurred vision or double vision.
- rash or skin redness.
- headache.
- dark-colored urine.
- feeling tired or dizzy.
- muscle or joint pain.

Additional side effects (of unknown frequency):
- tingling or numbness, stinging, pain or feeling weak in the arms or legs.
- unpleasant taste in the mouth, white tongue, nausea, vomiting, abdominal pain or diarrhea, loss of appetite.
- fever.
- depression.
- eye pain.
- in cases of prolonged treatment, peripheral sensory neuropathy or transient epileptic episodes (convulsions) have been reported.
- symptoms which together can indicate meningitis (an infection of the membranes that cover the brain and spinal cord): fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to light.
- liver injury, liver failure requiring a liver transplant has been reported in patients treated with metronidazole in combination with other antibiotic preparations.
- this medicine may cause a change in the color of the urine. This change is no reason for concern.

If any of the side effects worsen, or continue for more than a few days, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Dibasic calcium phosphate dihydrate, sodium starch glycolate, povidone, starch, magnesium stearate, colloidal silicon dioxide, talc, color FD&C yellow No. 6.

Each tablet contains 1.3-1.9 mg sodium.

What the medicine looks like and what are the contents of the package:
A round, light orange tablet, with a score line on one side and the other side is plain.
A package of 20 tablets is available.

Manufacturer, license holder and address:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah Tikva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
032.78.22672.00/03

This leaflet was checked and approved by the Ministry of Health in April 2014.

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