PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
This medicine is dispensed with a doctor's prescription only

FLAGYL 250 mg Tablets

Active ingredient and its quantity:
Each tablet contains metronidazole 250 mg
Inactive ingredients – see Section 2 "Important information about some of the ingredients of the medicine" and Section 6 "Further information".

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

1. WHAT IS THE MEDICINE INTENDED FOR?
The medicine is used for the treatment of infections caused by amebae, lambliasis, trichomonas, anaerobic bacteria, or bacteria sensitive to metronidazole.

Therapeutic group: Antibacterial, antiparasitic antibiotic from the 5-nitroimidazole group. ATC code: J01XD01-P01AB01.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient, or to any of the other ingredients of this medicine (see Section 6),
- you are allergic (hypersensitive) to wheat, as this medicine contains wheat starch (gluten),
- the patient is a child under 6 years of age (see Section "Special warnings regarding use of the medicine").

Special warnings regarding use of the medicine:
Before treatment with Flagyl 250 mg Tablets, inform the doctor if you have:
- neurological disorders,
- psychiatric disorders,
- blood disorders,
- ever had meningitis under metronidazole treatment.

If you are about to have a blood test, tell the doctor or nurse who is doing the test that you are taking Flagyl 250 mg Tablets. Flagyl 250 mg Tablets may affect the results of certain blood tests.

Refer to a doctor immediately if any of the following effects occur during treatment with Flagyl 250 mg Tablets:
From the first dose, there is a risk of severe and sudden allergic reaction (anaphylactic shock, large areas of hives), with the following symptoms: tight chest, dizziness, nausea or fainting, or dizziness on standing up (see Section 4 "Side effects"). If these symptoms occur, stop taking the medicine and immediately refer to a doctor, as it may be life-threatening.
The onset of a rash spreading all over the body with pustules, accompanied by fever at the beginning of treatment, suggests a serious reaction known as acute generalised exanthematous pustulosis (see Section 4 "Side effects"). Inform your doctor immediately, as this means that the treatment must be stopped. If such a reaction occurs, you must never again take metronidazole alone or combined with another active substance.
Watch out for potential onset or worsening of nervous disorders such as difficulty coordinating movements, dizziness (feeling like your "head is spinning"), confusion, convulsions, difficulty speaking and walking, tremors, involuntary eye movements, and other symptoms of the hands and feet, such as formication, tingling, feeling cold, numbness and reduced sense of touch. These symptoms are generally reversible on stopping treatment. It is therefore important to stop the treatment and consult your doctor immediately (see Section 4 "Side effects").
Behavioural disorders that pose a risk to the patient may occur as soon as the treatment is taken for the first time, especially in case of previous psychiatric disorders. You should stop the treatment and consult a doctor (see Section 4 "Side effects").
Cases of severe hepatotoxicity or acute liver failure, including cases of death in patients with Cockayne syndrome, have been reported with medicines containing metronidazole.
If you have Cockayne syndrome, your doctor must monitor your liver function frequently, both during and after treatment with metronidazole.
Tell your doctor immediately and stop taking metronidazole if you develop the following symptoms:
stomachache, lack of appetite, nausea, vomiting, fever, weakness, tiredness, jaundice, dark-coloured urine, putty- or resin-coloured stools or itching.

Children:
Do not give the tablets to children under 6 years of age due to risk of choking. Other dosage forms of this antibiotic are available for young children.
Talk to the doctor or pharmacist before taking Flagyl 250 mg Tablets.

Tests and follow-up:
If you had blood disorders in the past, or you are receiving a high and/or prolonged dosage, your doctor may refer you for periodic blood tests to check your complete blood count.
Inform the doctor or the analysis laboratory that you are taking this medicine if you have to have a laboratory test, as taking metronidazole may interfere with some laboratory test results (test for treponema) by giving a false positive result (e.g., Nelson test).

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, if you are taking:
- medicines containing alcohol because of the risk of side effects such as redness of the face, feeling hot, vomiting and increased heart rate,
- busulfan (recommended for the treatment of certain types of blood disorders and for the preparation for a bone marrow transplant),
- disulfiram (used to prevent relapse in alcohol-dependent patients),
- any medicine that could cause disturbances in heart rhythm (also called prolongation of the QT interval, visible on the electrocardiogram [ECG]), such as certain antiarrhythmics, certain antibiotics, and medicine used as first-line therapy in the management of psychoses (which include delusions, hallucinations, paranoia, or thought disorders),
- enzyme-inducing anticonvulsants, used in the treatment of epileptic seizures,
- rifampicin (recommended in the treatment of certain bacterial infections, including tuberculosis),
- lithium (used to treat mental illnesses),
- 5-fluorouracil (cancer medicine),
- oral blood thinners called vitamin K antagonists which are prescribed to prevent clots from forming.

Use of the medicine and alcohol consumption:
Avoid drinking alcohol while taking this medicine due to the risk of side effects such as redness of the face, feeling hot, vomiting and increased heart rate.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult with the doctor or pharmacist before taking this medicine.
If necessary, this medicine may be taken during pregnancy. However, you must always consult with the doctor or pharmacist before taking it.
Avoid breastfeeding while taking this medicine.

Driving and operating machinery:
Vehicle drivers and persons operating machinery should pay particular attention to the risks associated with the use of Flagyl 250 mg Tablets, such as dizziness (feeling like your "head is spinning"), confusion, hallucinations (seeing or hearing things that are not there), convulsions (convulsive seizures), or temporary vision problems (such as blurred or double vision).
If these symptoms occur, do not drive a vehicle or operate machinery.

Important information about some of the ingredients of the medicine:
Flagyl 250 mg Tablets contain gluten.
This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease.
One tablet contains no more than 8.215 micrograms of gluten.
If you have an allergy to wheat (different from coeliac disease), do not take this medicine (see section "Do not use the medicine if:").

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
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 your ailment.

The usual dosage is generally:
For amoebas:
Adults - 1.50 g/day, divided into 3 doses.
Children – 30-40 mg/kg body weight/day, divided into 3 doses.
Treatment duration - 7 consecutive days.
For trichomonas:
- Women (Trichomonas of the urethra and vagina) - 10-day treatment combining:
0.50 g/day by oral route, divided into 2 doses,
1 pessary/day.
If pessary form of administration is not available, the doctor will consider an alternative treatment.
The sex partner should also be treated concomitantly, regardless of occurrence of signs of infection and even with negative laboratory test results.
- Men (Trichomonas of the urethra):
0.50 g by oral route, divided into 2 doses, for 10 days.
In very rare cases, it will be necessary to increase the daily dosage to 0.750 g or 1 g.
For Lambliasis:
Adults - 0.750 g/day to 1 g/day, for 5 consecutive days.
Children from 6 to 10 years of age - 375 mg/day.
Children from 10-15 years of age - 500 mg/day.
For non-specific vaginitis:
500 mg twice daily for 7 days (250 mg x 2).
The sex partner should also be concomitantly treated.
For anaerobic bacteria:
Adults - 1 g/day to 1.5 g/day.
Children - 20-30 mg/kg body weight/day
Do not exceed the recommended dosage.
Swallow the tablet whole with water.
Do not crush or chew the tablet.
Take the tablet during a meal or immediately after completing one.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately 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 at the required time, take a dose as soon as you remember. However, if it is almost time for the next dose, skip this dose and take the next dose at the usual time and consult the doctor. Do not take a double dose to compensate for the forgotten dose.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

Individuals undergoing dialysis – dialysis clears Flagyl 250 mg Tablets from the blood. If you are undergoing dialysis, take Flagyl 250 mg Tablets after the dialysis treatment.

Individuals with liver problems – the doctor may instruct you to use a lower dosage than usual or less often than usual.

Tests and follow-up – the doctor may want to perform tests if you are taking the medicine for more than 10 days.

Do not take medicines in the dark! Check the label and the 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 Flagyl 250 mg Tablets may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Digestive disorders:
- digestive disorders that are not serious, such as stomachache, nausea, vomiting, diarrhoea,
- inflammation of the tongue and dry mouth, inflammation of the mouth, taste disorders, loss of appetite,
- pancreatitis (inflammation of the pancreas), which is reversible after stopping treatment,
- discolouration or change in the appearance of the tongue (may be caused by fungus).

Effects on the skin and mucous membranes:
- hot flushes with redness of the face, itching, rash sometimes accompanied by fever,
- urticaria (skin rash), sudden swelling of the face and neck caused by allergies (large areas of hives), life-threatening allergic shock (see Section 2 "Special warnings regarding use of the medicine"),
- very rare cases of rash spreading to the whole body, with pustules, accompanied by fever (acute generalised exanthematous pustulosis) (see Section 2 "Special warnings regarding use of the medicine"),
- a blistering rash with peeling of the skin which can spread to the whole body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome),
- fixed drug eruption: round, red patches of skin rash with an itchy, burning sensation, leaving coloured marks and possibly reappearing in the same places if treatment is resumed with the same medicine.

Nervous system disorders:
- nerve damage in the limbs (peripheral sensory neuropathy) with effects on the hands and feet such as tingling, pins and needles, feeling cold, numbness and reduced sense of touch,

- headache,
- dizziness (feeling like your "head is spinning"),
- seizures,
- confusion,
- neurological disorders, called encephalopathy or cerebellar syndrome, resulting in a state of confusion, consciousness disorders, behavioural disorders, difficulties in coordinating movements, pronunciation disorders, gait disorders, involuntary eye movements, tremor. These symptoms are generally reversible when treatment is stopped and may be associated with changes in medical imaging (MRI). Rare cases with fatal outcomes have been reported (see Section 2 "Special warnings regarding use of the medicine"),
- non-bacterial meningitis.

Psychiatric disorders:
- hallucinations,
- personality disorders (paranoia, delirium) that may be accompanied by suicidal thoughts or actions (see Section 2 "Special warnings regarding use of the medicine"),
- depressive tendency.

Vision disorders:
- temporary vision disorders such as blurred vision, double vision, short-sightedness, decreased vision, changes in colour vision,
- optic nerve damage or inflammation.

Blood disorders:
- abnormally low platelet counts, abnormally low or major drop in the number of certain white blood cells (neutrophils).

Cardiac disorders:
Frequency unknown (cannot be estimated from the available data): Heart rhythm disturbances (also called prolongation of the QT interval, visible on the electrocardiogram [ECG]), in particular when Flagyl 250 mg Tablets is used with other medicines likely to cause disturbances in the heart rhythm.

Effects on the liver:
- elevated liver enzymes (transaminases, alkaline phosphatase),
- very rare cases of serious liver damage (sometimes with jaundice), in particular, cases of liver failure requiring a transplant.

Other information:
- reddish-brown-coloured urine caused by the medicine.

If a side effect occurs, if any of the side effects worsen, or when you are suffering from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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.
Do not store at a temperature exceeding 30°C. Protect from light.
Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION:
In addition to the active ingredient, the medicine also contains:
Wheat starch, povidone K30, magnesium stearate, hypromellose, macrogol 20000.
What the medicine looks like and the contents of the package:
A round, white/cream-coloured, film-coated tablet. Packs of 20, 50 or 100 tablets. Not all pack sizes are marketed.

This leaflet does not contain all the information about the medicine. If you have any question or are not sure about anything, please refer to the doctor.

License Holder and Importer and its address: sanofi-aventis Israel ltd., P.O. Box 8090, Netanya.
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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 106 97 21742.