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

FLAGYL SUSPENSION

The active ingredient and its quantity:
Each 1 mL contains:
Metronidazole benzoate 40 mg
Corresponding to Metronidazole 25 mg
Each measuring spoon (5 mL) contains:
Metronidazole 125 mg

Inactive and allergenic ingredients in the preparation – see Section 2 "Important information about some of the ingredients of the medicine" and Section 6 "Further information".

Read the 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 has been 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 due to amebae, lambliasis, trichomonas, anaerobic bacteria, or bacteria sensitive to metronidazole.
The medicine contains an active ingredient called metronidazole, which belongs to a group of medicines called antibiotics.
The agent 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 have symptoms – please consult the doctor.

Therapeutic group: antibacterial, anti-parasitic antibiotic from the nitro-5-imidazoles family.
ATC code: J01XD01-P01AB01.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient metronidazole, or to a medicinal product from the imidazole family (family of antibiotics to which metronidazole belongs) or to any of the additional ingredients contained in the medicine (see Section 6).

Special warnings regarding use of the medicine:
Before treatment with Flagyl Suspension, tell the doctor if you have:
- neurological disorders,
- psychiatric disorders,
- blood disorders,
- History of meningitis while receiving 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 Suspension. This medicine may affect the results of some blood tests.
Refer to a doctor immediately if one or more of the following effects occur during treatment with Flagyl Suspension:

From the first dose, there is a risk of severe and sudden allergic reaction (anaphylactic shock, angioedema), which may cause the following symptoms: chest tightness, dizziness, nausea or fainting, or dizziness on standing up (see Section 4). If these symptoms occur, stop using the medicine because your life might be in danger, and immediately refer to a doctor.

If at the start of treatment, you notice redness all over the body with pustules, accompanied by fever, a serious reaction known as acute generalized exanthematous pustulosis should be suspected (see Section 4). Inform your doctor immediately as treatment must be stopped. This reaction will contraindicate any new administration of metronidazole, alone or in combination of the same medication with another active substance.

Watch out for potential signs or worsening of nervous disorders, such as difficulty coordinating movements, dizziness (feeling like your "head is spinning"), confusion, seizures, difficulty speaking or walking, tremor, involuntary eye movements, as well as other disturbances of the hands and feet, such as tingling, pins and needles, feeling cold, numbness and reduced sense of touch. These disorders are generally reversible on stopping treatment. It is therefore important to stop treatment with the medicine and talk to the doctor immediately (see Section 4).
From the very first doses of treatment, behavioural disorders that may put you at risk can occur, especially if you have had psychiatric disorders in the past. If this happens, stop taking the medicine and refer to a doctor (see Section 4).

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 effects:
stomach ache, loss of appetite, nausea, vomiting, fever, feeling sick, tiredness, jaundice, dark urine, clay-colored stools or itching.

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 testing laboratory that you are taking this medicine if you have to undergo a laboratory test, since taking metronidazole may affect some of the 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, sensation of heat, vomiting and increased heart rate,
- busulfan (recommended for the treatment of certain blood diseases and for 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 medicines used as first-line therapy in the management of psychoses (which includes delusions, hallucinations, paranoia, or thought disorders),
- enzyme-inducing anticonvulsants, used in the treatment of epileptic seizures,
- rifampicin (recommended for treatment of certain bacterial infections, including tuberculosis),
- lithium (used to treat mental illnesses),
- 5-fluorouracil (a cancer medicine)
- oral anticoagulants called vitamin K antagonists, prescribed to prevent formation of blood clots.

Use of the medicine and alcohol consumption:
Avoid drinking alcohol during the course of treatment with this medicine, due to the risk of side effects, such as redness of the face, sensation of heat, vomiting and increased heart rate.

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

Driving and using machinery:
If you drive a car or operate machinery, pay particular attention to the risks associated with the use of Flagyl suspension, 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 Suspension contains sucrose, ethanol, sodium and parahydroxybenzoate.
This medicine contains sucrose. Patients with fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase-isomaltase insufficiency (rare metabolic diseases) should not take this medicine.
This medicine contains 3 grams of sucrose in each measuring spoon. Take this into account for the daily intake calculation of patients on a low-sugar diet or with diabetes.
This medicine contains ethanol (alcohol) 1% v/v, namely, up to 40 mg ethanol per measuring spoon, equivalent to 12 ml of beer or 5 ml of wine per dose. Use of this medicine is harmful for people suffering from alcoholism. Take this into account in pregnant or breastfeeding women, in children and in high-risk groups, such as patients with liver disease or epilepsy.
This medicine contains less than 1 mmol (23 mg) of sodium per dose, i.e., it is essentially "sodium-free".
This medicine contains parahydroxybenzoate and may cause allergic reactions.

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 metronidazole, divided into 3 doses.
- Children – 30-40 mg/kg body weight/day metronidazole, 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 metronidazole by oral route, divided into 2 doses;
1 pessary/day.

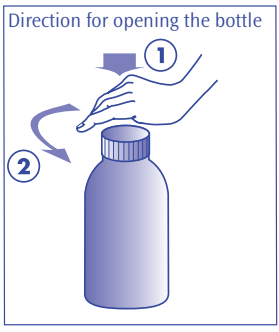
If pessary form of administration is not available, the doctor will consider an alternative treatment.
The sexual partner should also be treated concomitantly, regardless of occurrence of signs of infection and even with negative laboratory test results.
- Men (Trichomonas of the urethra):
0.50 g/day metronidazole by oral route, divided into 2 doses, for 10 days.

In very rare cases, it will be necessary to increase the dosage to 0.750 g or 1 g metronidazole.
For Lambliasis:
- Adults - 0.750 g/day to 1 g/day metronidazole, for 5 consecutive days.
- Children aged 2 to 5 years of age - 250 mg/day metronidazole.
- Children aged 5 to 10 years of age - 375 mg/day metronidazole.
- Children aged 10 to 15 years of age - 500 mg/day metronidazole.

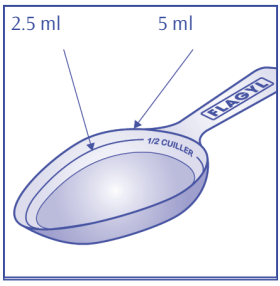
Non-specific vaginitis:
500 mg metronidazole twice daily for 7 days (250 mg x 2).
The sexual partner should also be concomitantly treated.
For anaerobic bacteria:
- Adults - 1 g/day to 1.5 g/day metronidazole.
- Children - 20-30 mg/kg body weight/day metronidazole.

Do not exceed the recommended dosage.
The suspension should be shaken before use.
Use the measuring spoon provided with the package to measure the correct amount of medicine. Do not use a household spoon to measure the amount of medicine. Household teaspoons differ in their size and you may not receive the proper amount of medicine.

Instructions for taking the medicine:
1. To open the bottle, press down and turn the child-resistant cap, as shown in the diagram below:



2. This medicine is administered using a measuring spoon for oral administration supplied in the package with the bottle. The use of this measuring spoon is intended for oral administration of Flagyl Suspension only.
   Use this measuring spoon for oral administration to measure the dose of metronidazole to be taken.
   A full measuring spoon corresponds to a dose of 125 mg of metronidazole (i.e., a volume of 5 ml).
   It is possible to administer a dose of 62.5 mg of metronidazole, using the measuring spoon filled to the level of the "½ spoon" mark (i.e., a volume of 2.5 ml).
   Other amounts of metronidazole can be given with this measuring spoon. For example, to give a 250 mg dose of metronidazole, fill the measuring spoon to the top, administer the dose and then repeat the process a second time.
   Diagram of the measuring spoon:



   One measuring spoon filled to the top (5 ml) contains 125 mg metronidazole.
   Half a measuring spoon filled to the "1/2 CUILLER" mark (2.5 ml) contains 62.5 mg metronidazole.

3. After each use, close the bottle of the suspension, thoroughly wash the measuring spoon for oral administration with water and dry it. Then immediately store the measuring spoon for oral administration in its package in a place out of the reach and sight of children. Never separate the measuring spoon for oral administration from the other packaging elements of the medicine (bottle, package, patient leaflet).

Individuals undergoing dialysis – dialysis clears Flagyl Suspension from the blood. If you are undergoing dialysis, take Flagyl Suspension 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 take the medicine for more than 10 days.

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 the doctor.

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 Suspension 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 abdominal pain, nausea, vomiting, diarrhea,
- inflammation of the tongue and dry mouth, inflammation of the mouth, taste disorders, loss of appetite,
- pancreatitis (inflammation of the pancreas), which is reversible on stopping treatment,
- discoloration or change in the appearance of the tongue (may be caused by fungus).

Skin and subcutaneous tissue disorders:
- 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 (angioedema), life-threatening allergic shock (see Section 2, under "Special warnings regarding use of the medicine"),
- very rare cases of redness spreading to the whole body with pustules and fever (acute generalized exanthematous pustulosis) (see section 2, under "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 (Lyell's syndrome, Stevens-Johnson syndrome),
- fixed pigmented erythema: skin rash with round, red patches with an itchy, burning sensation leaving colored 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, with symptoms including confusion, consciousness disorders, behavioral disorders, difficulty coordinating movements, problems with pronunciation, balance disorders, involuntary eye movements, tremor. These disorders are generally reversible on stopping treatment and may be associated with changes in MRI scans. Exceptional cases of death have been reported (see Section 2, under "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, under "Special warnings regarding use of the medicine"),
- depressive tendency.

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

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

Cardiac disorders:
- unknown frequency (frequency 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 Suspension is used with other medicines likely to cause disturbances in the heart rhythm.

Hepatobiliary disorders:
- elevated liver enzymes (transaminases, alkaline phosphatases),
- very rare cases of serious liver damage (sometimes accompanied by jaundice), in particular cases of liver failure requiring a transplant.
- unknown frequency (frequency cannot be estimated from the available data): acute liver failure in patients with Cockayne syndrome (see section 2, under "Special warnings regarding use of the medicine").

Additional effects:
- reddish-brown-colored 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.

Store in a place protected from light, at a temperature that does not exceed 30°C.

After first opening, may be used for 8 days, and stored at a temperature that does not exceed 30°C.

Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. Once you have finished the treatment, return all the open packages of the medicine, including the measuring spoon and bottle, to the pharmacist, so that they can be correctly and appropriately destroyed. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Ready-to-use sucrose solution/sucrose powder, Ph. Eur., ethanol 96%, aluminium magnesium silicate, saccharin sodium, sodium dihydrogen phosphate dihydrate, methyl parahydroxybenzoate, concentrated lemon essence, deterpenated orange essence, propyl parahydroxybenzoate, purified water.

What the medicine looks like and the contents of the pack:
The suspension is grayish-white in color, with an orange-lemon scent. The preparation is packaged in a glass bottle and closed with a child-resistant cap. A measuring spoon is provided.
Pack size: 120 ml.

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

License Holder and Importer and its address: Sanofi Israel Ltd, Greenwork Park, P.O. box 47, Yakum.

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 104-56-22129.