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

The medicine is dispensed with a doctor's prescription only

FLAGYL SUSPENSION

SANOFI

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 ingredients – see Section 2 "Important information about some of the ingredients of the medicine" and Section 6.

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 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 a medicine belonging to the imidazole group (the group of antibiotics that metronidazole belongs to) 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, tell the doctor if you have:
- neurological disorders,
- psychiatric disorders,
- blood disorders,
- you have had meningitis in the past during treatment with metronidazole.

Refer to a doctor immediately if one or more of the following effects occur during treatment with Flagyl:

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 "Side effects"). 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 "Side effects"). Inform your doctor immediately as this requires treatment to be stopped. This reaction will mean that metronidazole should never be taken again, 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, 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 see a doctor immediately (see Section 4 "Side effects").

From the very first doses of treatment, your behavior may change and put you at risk, especially if you have had psychiatric problems in the past. If this happens, stop taking the medicine and refer to 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 effects:
stomach pain, lack of appetite, nausea, vomiting, fever, weakness, 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 types of blood disorders and for preparation for a bone marrow transplant),
- disulfiram (used to prevent relapse in alcohol-dependent patients),
- enzyme-inducing anticonvulsants (used to treat epilepsy),
- rifampicin (recommended for treatment of certain bacterial infections, such as tuberculosis),
- lithium (used to treat mental illnesses),
- 5-fluorouracil (chemotherapeutic 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 operating machinery:

You should take into account, especially if you drive or use machines, that there is a risk of dizziness, confusion, hallucinations, seizures and visual disturbances associated with this medicine.

Important information about some of the ingredients of the medicine:

Flagyl Suspension contains sucrose, ethanol, sodium and parahydroxybenzoate.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, difficulty absorbing glucose-galactose or sucrase-isomaltase insufficiency 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, which is equivalent to 12 ml beer or 5 ml wine per dose. Use of this preparation 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 sodium (23 mg) 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.

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 with a measuring spoon for oral administration supplied in the package with the bottle. This measuring spoon is intended for oral administration of Flagyl Suspension only.

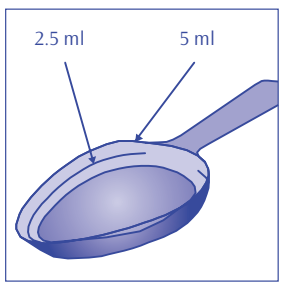
   Use this measuring spoon for oral administration to measure the dose of metronidazole to be taken.

   The total volume of the measuring spoon filled to the top is 5 ml, or a 125 mg dose of metronidazole.

   It is possible to administer 2.5 ml, or a 62.5 mg dose of metronidazole, by using the measuring spoon filled to the "1/2 teaspoon" mark.

   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.

   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 teaspoon" 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. Immediately place the measuring spoon for oral administration back in the package and store it out of the reach of children. Never separate the measuring spoon for oral administration from the other items in the package of the medicine (bottle, package, patient leaflet).

Individuals undergoing dialysis – dialysis clears Flagyl from the blood. If you are undergoing dialysis, take Flagyl 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 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 after stopping treatment,
- discoloration 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,
- skin rash, sudden allergic swelling of the face and neck (angioedema), allergic shock which could be life-threatening (see "Special warnings regarding use of the medicine"),
- very rare cases of redness spreading to the whole body with pustules, accompanied by fever (acute generalized exanthematous pustulosis) (see "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 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,
- vertigo,
- 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. Very rare cases of death have been reported (see "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 "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 color 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).

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

Other information:
- 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 up to 8 days, when 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. After completing the treatment, bring the open packages (including the measuring spoon and bottle) to the pharmacist, who will dispose of them as required. 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 package:
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.

Package size: 120 ml.

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.

Revised in February 2022 according to MOH guidelines.

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