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

The medicine is dispensed with a doctor's prescription only

FLAGYL SUSPENSION

SANOFI

Active ingredient and its concentration:
Metronidazole 2.5% (as benzoate)
Each measuring spoon (5 ml) contains:
Metronidazole 125 mg
Inactive ingredients - see Section 6.

Read the package insert carefully in its entirety before using the medicine.
Keep this leaflet, you may need to read it again.
This leaflet contains concise information about the medicine.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
If a side effect worsens, or if a side effect not mentioned in this leaflet appears, please refer to a doctor or pharmacist.
If you have additional questions, refer to the doctor or pharmacist.

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, that 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 experience any symptoms – please consult the doctor.

Therapeutic group: An imidazole antimicrobial.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
you are sensitive to metronidazole, nitroimidazole (e.g., tinidazole) or any of the other ingredients of the medicine (see Section 6).

Special warnings regarding use of the medicine:
Before treatment with the medicine, inform the doctor if:
- you have or have ever had impaired function of the liver.
- you are having kidney dialysis (see Section 3).
- you have a disease related to the nervous system.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:
- Medicines used to thin the blood, such as warfarin.
- Lithium given for mental illness.
- Phenobarbital or phenytoin for epilepsy.
- 5 fluorouracil for cancer.
- Busulfan for leukemia (cancer of the blood cells).
- Cyclosporine to prevent graft rejection.
- Disulfiram for alcoholism.

Use of Flagyl with food and drink/alcohol consumption:
Do not drink wines or alcoholic beverages while under treatment with Flagyl and during the 48 hours following completion of treatment. Alcohol consumption while taking Flagyl can cause unpleasant side effects, such as nausea, vomiting, abdominal pain, hot flashes, rapid or irregular heart rate and headache.

Pregnancy and breastfeeding:
Tell the doctor before starting treatment with Flagyl, if you are pregnant, plan to become pregnant or think you may be pregnant, or if you are breastfeeding. Do not take Flagyl during pregnancy or while breastfeeding, unless there is an absolute need for treatment.

Driving and operating machines:
While taking Flagyl, you may feel sleepy, suffer from dizziness, confusion, hallucinations (seeing or hearing things that do not exist), spasms or temporary vision problems (such as blurred or double vision).
If these effects occur, do not drive or operate machines or equipment.

Important information regarding some of the ingredients of the medicine:
- This preparation contains sucrose - each 5 ml contains 3 grams sucrose.
  Consult your doctor before commencing treatment with the medicine if you have an intolerance to fructose, problems absorbing glucose and galactose or a sucrase-isomaltase deficiency.
- The preparation contains alcohol - each 5 ml contains 40 mg alcohol.
- The preparation contains methylhydroxybenzoate and propylhydroxybenzoate, which may cause an allergic reaction.

If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure.
It is important that you complete the full course of treatment. The dosage and treatment regimen depend on your ailment; the dosage will be determined by the doctor.
Shake the suspension before use.
Use the measuring spoon provided with the package, to measure the correct amount of medicine. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons differ in their size and you may not receive the proper amount of medicine.
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.
Testing and monitoring – the doctor may want to perform tests if you take the medicine for more than 10 days.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or 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 a missed dose.
How can you contribute to the success of the treatment? Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with Flagyl without consulting the doctor or pharmacist.
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 additional 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 when reading the list of side effects. You may not suffer from any of them.

Stop treatment with the medicine and refer immediately to a doctor or a hospital if you notice the following side effects:
- Swelling of the hands, legs, ankles, face, lips or throat, that can cause difficulty swallowing or breathing. You may also notice itching or a rash. All of these may indicate that you are suffering from an allergic reaction to Flagyl.
- A severe, widespread skin rash that can include blistering or peeling of the skin (Stevens-Johnson syndrome, Toxic epidermal necrolysis).
- Brain injury (encephalopathy) is a serious but very rare effect. The symptoms of this effect vary, but you may suffer from fever, stiff neck, headache, seeing or hearing things that do not exist (hallucinations). You may also experience difficulty in moving the arms and legs, speech problems or a feeling of confusion.

Refer to the doctor immediately if you notice the following side effects:
- Yellowing of the skin and the eyes. Can arise from liver problems (jaundice).
- Unexpected infection, mouth ulcers, bruises, bleeding of the gums or severe fatigue. Can arise from blood problems.
- Severe abdominal pain that can radiate to the back (may indicate pancreatitis).

Refer to the doctor or pharmacist if you notice the following side effects:
Side effects that appear very rarely (occur in less than 1 of 10,000 people):
Fits, mental problems, such as a sensation of confusion and hallucinations (seeing or hearing things that do not exist), problems with your eyesight, such as blurred or double vision, rash or skin redness, headache, dark-colored urine, feeling tired or dizzy, muscle or joint pain.
Additional side effects that may occur (of unknown frequency):
Tingling or numbness, stinging, pain or feeling weak in the arms or legs, unpleasant taste in the mouth, tongue discoloration or furred tongue (for example, as a result of a fungal infection), nausea, vomiting, abdominal pain or diarrhea, loss of appetite, fever, depressed mood, eye pain.
In cases of prolonged treatment, peripheral sensory neuropathy or transient epileptic episodes (convulsions) have been reported.
A group of symptoms which together can indicate an infection of the membranes that cover the brain and spinal cord (meningitis): 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 conjunction with other antibiotic preparations.
If any of the side effects worsen or persist for more than a few days, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects and drug interactions in children and in infants:
Parents must report to the attending doctor about any side effect as well as any additional medicine being given to the child!

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicines, should be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.
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.
Shelf-life after first opening: 8 days.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Sucrose solution/powder, Ethanol 96, Magnesium silico aluminate, Sodium (5 mg/5 ml), Sodium dihydrogen phosphate dihydrate, Methyl parahydroxybenzoate, Concentrated lemon essence, Deterpenated orange essence, Propylparabenzoate, Purified water.
Each teaspoon (5 ml) contains 3 grams sucrose and 40 mg alcohol.

What does the medicine look like and what are 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, closed with a child-resistant cap.
Package size: 120 ml.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.
Manufacturer and address: Unither Liquid Manufacturing, France.
License holder and address: sanofi-aventis Israel ltd., P.O.Box 8090, Netanya 4250499.
This leaflet was checked and approved by the Ministry of Health in October 2013.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 104-56-22129-00.