

PACKAGE LEAFLET: INFORMATION FOR THE USER
Flagyl® 125 mg/5 ml, oral suspension
metronidazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Flagyl is and what it is used for
2. What you need to know before you take Flagyl
3. How to take Flagyl
4. Possible side effects
5. How to store Flagyl
6. Contents of the pack and other information

1. WHAT FLAGYL IS AND WHAT IT IS USED FOR

Flagyl is an antibacterial and antiparasitic antibiotic belonging to the 5-nitroimidazole group of medicines.

This medicine is used to treat certain infections caused by bacteria or parasites that are sensitive to Flagyl.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLAGYL

Contra-indications

Do not take Flagyl if:

- you are allergic to metronidazole or to a medicine belonging to the imidazoles class (the class of antibiotics to which metronidazole belongs) or any of the other ingredient of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Flagyl.

Talk to your doctor before taking Flagyl if you have:

- neurological disorders,
- psychiatric disorders,
- blood disorders,
- ever had meningitis while receiving metronidazole treatment.

Tell your doctor immediately if any of the following problems occur **during treatment with Flagyl:**

From the first dose, there is a risk of severe and sudden allergic reaction (anaphylactic shock, angioedema) possibly causing the following symptoms: tight chest, dizziness, nausea or fainting, or dizziness on standing up (see "Possible side effects"). If these symptoms occur, stop taking this medicine because your life might be in danger and, immediately contact your doctor.

If, at the start of treatment, you observe redness all over the body with pustules, accompanied by fever, a serious reaction known as acute generalized exanthematous pustulosis should be suspected (see "Possible side effects"). Tell your doctor immediately, as treatment must be stopped. If such a reaction occurs, you should never again take metronidazole alone or in combination with another active substance in the same medicine.

You should watch out for any potential signs or worsening of nervous disorders such as difficulty coordinating movements, confusion, seizures, difficulty speaking or walking, shakiness, involuntary eye movements, as well as other effects on 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 taking this medicine and see a doctor immediately (see "Possible side effects").

From the very first doses of treatment, your behavior may alter and put you at risk, especially if you have had psychiatric problems in the past. If this happens, you should stop taking the medicine and see a doctor (see "Possible side effects").

If you have had blood disorders in the past, or are receiving high-dose and/or long-term treatment, your doctor may prescribe regular blood tests to check your complete blood count.

Inform the doctor or analysis laboratory that you are taking this medicine if you have to have a medical laboratory test, as taking metronidazole may interfere with some laboratory test results (test for treponema) by triggering a false positive result (e.g. the Nelson test).

Cases of severe hepatotoxicity/acute liver failure, including cases with a fatal outcome 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 your treatment with metronidazole.

Tell your doctor immediately and stop taking metronidazole if you have the following symptoms:

- Stomach ache, anorexia, nausea, vomiting, fever, feeling faint, tiredness, jaundice, dark-colored urine, putty-colored stools or itching.

Other medicines and Flagyl

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor 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 of a bone marrow transplant),
- disulfiram (used to prevent relapse in alcohol-dependent patients).

Flagyl with food and drink

You should 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 breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If necessary, this medicine may be taken during pregnancy. However, you must always ask your doctor or pharmacist for advice before taking it.

You should avoid breast-feeding while taking this medicine.

Driving and using machines

You should be aware, particularly if you drive or use machines, that there is a risk of dizziness, confusion, hallucinations, convulsions or vision disorders associated with this medicine.

Flagyl contains sucrose, ethanol, sodium, and parahydroxybenzoate.

This medicine contains sucrose. Patient with fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase insufficiency (rare metabolic diseases) should not take this medicine.

This medicine contains 3 g of sucrose per measuring spoon. This should be taken into account as part of the daily intake for patients on a low-sugar diet or with diabetes.

This medicine contains 1% v/v ethanol (alcohol), i.e. up to 40 mg of alcohol per measuring spoon, which is equivalent to 12 ml of beer or 5 ml of wine per dose. Use of this medicine is dangerous in alcoholics. This should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

This medicine contains sodium. The sodium content is less than 1 mmol per dose, in other words it is essentially "sodium-free".

This medicine contains a "parahydroxybenzoate" and may cause allergic reactions.

3. HOW TO TAKE FLAGYL

The dosage depends on your age and the illness being treated.

As an indication, the usual dose is:

- Adults: 0.50 g/day to 1.5 g/day.
 - Children: 250 mg/day to 20-40 mg/kg/day.
- In some cases, it is essential that your partner be treated, whether or not he/she has any clinical signs of the same infection.

In all cases, follow your doctor's prescription.

Oral use.

Frequency of administration

2 or 3 times per day, depending on why you are taking the medicine.

Treatment duration

In order to be effective, this antibiotic must be taken regularly at the prescribed doses and for as long as your doctor advises.

If your fever or any other symptom disappears, it does not mean that you are cured.

If you feel tired, this is not due to the antibiotic treatment but to the infection itself. Reducing or stopping your treatment would have no effect on this feeling and would only delay your recovery.

Special cases: treatment of giardiasis (infection caused by a parasite) should last 5 days, treatment of amebiasis (infection caused by a parasite) and some types of vaginitis (infection of the vagina), 7 days and treatment of trichomoniasis (infection caused by a parasite), 10 days.

If you have taken more Flagyl than you should:

Consult your doctor or pharmacist immediately. If you are vomiting, have difficulty coordinating your movements or are disorientated, consult your doctor. Your doctor may decide to prescribe appropriate treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Digestive disorders

- digestive disorders that are not serious, such as stomach ache, 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 fungal growth).

Effects on the skin and mucous membranes

- hot flushes with redness of the face, itching, skin rashes sometimes accompanied by fever,
- hives (skin rash similar to nettle rash), sudden allergic swelling of the face and neck (angioedema), allergic shock which could be life-threatening (see "What you need to know before you take Flagyl"),
- very rare cases of redness spreading to the whole body with pustules, accompanied by fever (acute generalized exanthematous pustulosis) (see "What you need to know before you take Flagyl"),
- 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, pricking, feeling cold, numbness and reduced sense of touch,
- headache,
- dizziness,
- seizures,
- confusion,
- neurological disorders, known as encephalopathy or cerebellar syndrome, with symptoms including confusion, consciousness disorders, behavioral disorders, difficulty coordinating movements, problems with pronunciation, gait disorders, involuntary eye movements, shakiness. These disorders are generally reversible on stopping treatment and may be associated with changes in MRI scans. Very rare cases of fatal outcome have been reported (see "What you need to know before you take Flagyl").
- non-bacterial meningitis.

Psychiatric disorders

- hallucinations,
- personality disorders (paranoia, delirium) that may be accompanied by suicidal thoughts or actions (see "What you need to know before you take Flagyl"),
- depressive tendency.

Vision disorders

- temporary vision disorders such as blurred vision, double vision, short-sightedness, decreased vision, changes in color vision,
- optic nerve damage/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 disease (sometimes with jaundice), in particular cases of liver failure requiring a transplant.

Other effects

- reddish-brown colored urine caused by the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLAGYL

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not take this medicine after the expiry date which is stated on the bottle.

This medicine must be stored protected from light at a temperature no higher than 30°C.

After opening the bottle: this medicine should be stored for 8 days maximum.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flagyl 125 mg/5 ml, oral suspension contains

The active substance is:

metronidazole.....2,5g
(equivalent to 4 g of metronidazole benzoate)
for 100 ml.

One measuring-spoon (5 ml) is equivalent to 125 mg of metronidazole.

The other ingredients are: Sodium dihydrogen

phosphate, methyl paraben (E218), propyl paraben (E216), special magnesium aluminum silicate (veegum), sucrose, saccharin sodium dihydrate, ethyl alcohol 95% (v/v), concentrated lemon oil, deterpenated sweet orange essence, purified water.

What Flagyl oral suspension looks like and contents of the pack

This medicine is supplied as an oral suspension. Bottle of 120 ml and a measuring-spoon (5 ml).

Marketing Authorization Holder

sanofi-aventis France
82, avenue Raspail - 94250 Gentilly- France

Manufacturer

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HEALTH ADVICE / EDUCATION

WHAT YOU SHOULD KNOW ABOUT ANTIBIOTICS

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against infections caused by viruses.

Your doctor has chosen to prescribe this antibiotic for you because it is suitable specifically for you and for the disease you have.

Bacteria are able to survive or to reproduce despite the effects of antibiotics. This is known as resistance and makes some antibiotic treatments ineffective. Taking antibiotics too often or when they are not necessary increases this resistance.

You may promote the growth of resistant bacteria and therefore slow down your recovery, or even make this medicine ineffective, if you do not follow the instructions concerning:

1. how much of the medicine to take
2. when to take it
3. how long the treatment should last

Therefore, to maintain the effectiveness of this medicine:

- 1) Use an antibiotic only when your doctor has prescribed it for you.
- 2) Comply strictly with your prescription.
- 3) Do not reuse an antibiotic without a prescription, even if you think you have a similar disease.
- 4) Never give your antibiotic to someone else, as it may not be appropriate for their disease.
- 5) Once you have finished your treatment, take all opened boxes of the medicine to your pharmacist to be thrown away safely.