

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flagyl® 250 mg film-coated tablets

metronidazole

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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. 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.

It is used to treat certain infections caused by bacteria or parasites that are sensitive to Flagyl (called “susceptible micro-organisms”).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLAGYL

Contra-indications :
Do not take Flagyl:

- if you are allergic to metronidazole, to any medicine in the imidazole group (the group of antibiotics that includes metronidazole) or to any other ingredient of this medicine listed in Section 6.
- if you are allergic (hypersensitive) to wheat, as this medicine contains wheat starch (gluten),
- if the patient is a child under 6 years of age (see “Warnings and precautions”).

Appropriate precautions for use ; Special warnings: Warnings and precautions for use
Before taking **Flagyl**, tell your doctor if you have:

- neurological disorders,
- psychiatric disorders,
- blood disorders,
- ever had meningitis under 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 when standing up (see “Possible side effects”). If these symptoms occur, stop taking this medicine because your life might be in danger and immediately contact a doctor.

If, at the start of treatment, you experience redness all over the body and pustules, accompanied by fever, a serious reaction known as acute generalized exanthematous pustulosis should be suspected (see “Possible side effects”); inform your doctor immediately as treatment must be stopped. Any further administration of metronidazole alone or in combination with another active substance in the same medicine is contraindicated if such a reaction occurs. You should watch out for any signs or potential aggravation 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, pricking, feeling cold, numbness and reduced sense of touch. These disorders are generally reversible on treatment discontinuation. 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 received 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: taking metronidazole may interfere with on some laboratory test results (test for treponema), by triggering a false positive result for a test (Nelson test).

Children
The administration of tablets is contraindicated in children under 6 years of age due to the risk of choking. Other dosage forms of this antibiotic that are more suitable for young children are available.

Talk to your doctor or pharmacist before taking Flagyl.

Other medicines and Flagyl
Tell your doctor or pharmacist if you are taking, have recently taken or may 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 alcohol
Drinking alcoholic beverages should be avoided during treatment because of the risk of side effects such as redness of the face, feeling hot, vomiting and increased heart rate.

Pregnancy and breast-feeding
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. 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.

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.

Important information about some of the ingredients of Flagyl
This medicine can be used in patients with celiac disease. Wheat starch can contain gluten, but only traces, and is therefore considered safe for patients with celiac disease.

3. HOW TO TAKE FLAGYL

How much Flagyl should be taken
This medicine is for adults and children at least 6 years of age only. More suitable dosage forms are available for children under 6 years of age.
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: 375 mg/day - 20 to 40 mg/kg/day.

In some cases, it is essential that your partner be treated, whether or not he/she has any clinical signs.

IN ALL CASES, FOLLOW YOUR DOCTOR'S PRESCRIPTION.
How Flagyl should be taken
Oral route.
Swallow the tablets with water.

How often Flagyl should be taken
2 to 3 times a day, depending on the infection being treated.
How long Flagyl should be taken
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:
If you are vomiting, have difficulty coordinating your movements or are disorientated, consult your doctor. Your doctor may decide to prescribe treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Flagyl** can cause side effects, although not everybody gets them.

Digestive disorders

- digestive disorders that are not serious, such as stomach pains, 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 (angio-edema), 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 rapidly spread to the whole body and be life-threatening (toxic epidermal necrolysis, Stevens-Johnson syndrome).

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, pronunciation disorders, gait disorders, involuntary eye movements, shakiness. These disorders are generally reversible on treatment discontinuation 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.

Mental disorders

- hallucinations,
- personality disorders (paranoia, delusion) possibly with suicidal ideas or attempts (see “What you need to know before you take Flagyl”),
- depressive tendencies.

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 accompanied by 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 Flagyl after the expiry date which is stated on the outer packaging.
Do not store above 30°C.
Keep the blisters in the outer packaging, protected from light.
Do not throw away any medicines via wastewater or household waste.
Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. OTHER INFORMATION

What Flagyl 250 mg film-coated tablets contains
The active substance is:
Metronidazole.....250 mg
for one film-coated tablet.

The other ingredients are:
Wheat starch, povidone K30, magnesium stearate, hypromellose, macrogol 20000.
What Flagyl film-coated tablets looks like and contents of the pack
This medicine is supplied as film-coated tablets.
Box of 20.

Marketing Authorization Holder
sanofi-aventis France
82, avenue Raspail
94250 Gentilly – France
Manufacturer
sanofi-aventis S.A.
Ctra. C-35 – La Batlloria a Hostalric, Km 63,09
17404 - Riells i Viabrea (Gerona) - Spain
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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.**