

Flagyl™-S 200mg/5ml Oral Suspension

metronidazole



Is this leaflet hard to see or read? Phone 01 403 5600 for help.

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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- 1. What Flagyl is and what it is used for**
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1. WHAT FLAGYL IS AND WHAT IT IS USED FOR

Flagyl belongs to a group of medicines called anti-microbials. Flagyl is used in the treatment and prevention of severe infections that are caused by anaerobic bacteria, particularly species of *Bacteroides*, anaerobic *Streptococci*, *Fusobacteria*, *Clostridia*, etc.

It works by killing bacteria and parasites that cause infection in your body.

It can be used to:

- Treat infections of the genital tract, pelvic area, stomach and intestines.
- Treat gum ulcers and other dental infections.
- Treat infected leg ulcers and pressure sores.
- Prevent infections after surgery.
- In the prevention and treatment of infections due to anaerobic bacteria (bacteria that are able to survive in the absence of oxygen)

If you need any further information on your illness, speak to your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLAGYL

Do not take Flagyl:

- If you are sensitive or allergic to metronidazole or any of the ingredients listed below in Section 6. Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are pregnant or breast feeding or think you might be pregnant.
- If you are suffering or have ever suffered from any liver or kidney disease.
- If you are suffering or have ever suffered from any diseases of the nervous system.

Warnings and Precautions

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with product containing metronidazole.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards.

Tell your doctor immediately and stop taking metronidazole if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Flagyl. Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. It may also include ulcers in the mouth, throat, nose or genitals. If you develop any of the above you must stop taking your medicine and inform your doctor straight away (see Section 4).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Flagyl can affect the way some medicines work. Also, some other medicines can affect the way Flagyl works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines used to thin the blood, such as warfarin
- Lithium (used to treat depression)
- Disulfiram (used to treat alcoholism)
- Phenobarbital or Phenytoin (used to treat epilepsy)
- Cyclosporin (used to treat arthritis and some skin conditions)
- 5-fluorouracil (used in the treatment of cancer).
- Busulfan (used in the treatment of leukaemia).

Taking Flagyl with food and drink

Do not drink any alcohol while you are taking Flagyl and for 48 hours after finishing your course. Drinking alcohol while using Flagyl might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heart beat (palpitations) and headache.

Pregnancy and breast-feeding

Tell your doctor before using Flagyl if:

- You are pregnant, might become pregnant or think you may be pregnant. Flagyl should not be taken during pregnancy unless considered absolutely necessary.
- If you are breast-feeding. It is better not to use Flagyl if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Driving and using machines

Whilst taking Flagyl you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

Tests

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

Important information about some of the ingredients of Flagyl

This product contains sucrose. Each dose contains up to 3.01g sucrose. This should be taken into account in patients with diabetes mellitus.

This product also contains 0.8% of ethanol. Each dose contains up to 0.032g of alcohol.

3. HOW TO TAKE FLAGYL

Taking your medicine

Always take Flagyl exactly as your doctor has told you. Shake the bottle gently before each use.

It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

Check with your doctor or pharmacist if you are not sure.

- Take Flagyl Suspension by mouth
- The dose of Flagyl will depend on your needs and the illness being treated
The length of your treatment will depend on the type of illness you have and how bad it is
- Your doctor or pharmacist may dilute your Flagyl Suspension. In this case the pharmacist's label on the packaging will tell you exactly how much to take and how often.

The usual dose for adults and children is given below:

To treat certain bacterial infection

Adults and children over 10 years

- Take 10ml (400mg) of Flagyl Suspension once every 8 hours

Children and infants

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours

If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly.

To Prevent infections from happening after surgery

Children:

Give your child Flagyl 2-3 hours before their operation.

Your doctor will work out how much your child should take depending on their weight.

Other types of infections

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Flagyl you need to take. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you exactly how much Flagyl Suspension to take and how often.

People having kidney dialysis

Kidney dialysis removes Flagyl from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

People with liver problems

Your doctor may tell you to use a lower dose or to use the medicine less often.

If you take more Flagyl than you should

If you take more Flagyl than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the pack with you. This is so the doctor knows what you have taken.

If you forget to take Flagyl

If you forget to take Flagyl, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

If you stop taking Flagyl

You should only stop taking Flagyl if your doctor tells you to. It is essential to take the medicine and not to stop and start as this could cause unwanted side effects.

4. POSSIBLE SIDE-EFFECTS

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

Tell your doctor or pharmacist straight away if you notice any of the following side effects:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Flagyl.
- You experience blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
- You have a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis'.
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.
- You develop symptoms such as abnormal sensitivity to light, abdominal pain, fever these could be symptoms of meningitis.
- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bleeding gums, severe tiredness or weakness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis).

Tell your doctor or pharmacist if you notice any of the following side effects:

- Fits (convulsions)
- Mental problems such as feeling confused or seeing or hearing things that are not there (hallucinations).
- Problems with your eyesight such as blurred or double vision, changes in colour vision
- Tingling or burning pain in your eye
- Hearing problems, ringing in ears (tinnitus)
- Skin rash, flushing, itching

- Headache
- Darkening of the urine
- Diarrhoea
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Numbness, tingling, pain or a feeling of weakness in the arms or legs
- Fever
- Unpleasant taste in the mouth
- Furred tongue, dry mouth
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite, anorexia
- Depression

All medicines may have unwanted effects which are not mentioned in the package leaflet. If you notice any other changes in your health whilst taking this medicine, tell your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

5. HOW TO STORE FLAGYL

Do not store above 25°C. Store in the original container in order to protect the product from the light. After opening discard any unused suspension after 28 days.

Flagyl-S 200mg/5ml Oral Suspension may be diluted, if necessary, with Syrup BP. Discard any unused diluted suspension after 14 days. Keep your medicine in a safe place, out of the reach and sight of children.

Do not use Flagyl-S 200mg/5ml Oral Suspension after the expiry date which is stated on the bottle label and carton after 'EXP'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flagyl contains

The active substance in Flagyl is Metronidazole. Each 5ml of suspension contains Metronidazole Benzoate equivalent to 200mg of Metronidazole.

The oral suspension also contains the following ingredients: Sucrose, Sodium Dihydrogen Phosphate Dihydrate (E339), Aluminium Magnesium Silicate, Methyl Parahydroxybenzoate (E218), Propyl Parahydroxybenzoate (E216), Ethanol (96% v/v), 0.8%, Lemon Flavour (contains propylene glycol), Orange Oil Terpeneless and Purified Water.

What Flagyl looks like and contents of the pack

Flagyl is a white to cream coloured oral suspension and is available in bottles of 100ml suspension packed in an outer carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

sanofi-aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24.
Tel: 01 403 5600
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Email: IRemedinfo@sanofi.com

Manufacturer:

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31770 Colomiers,
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