

Flagyl™ 0.5% w/v Solution for Infusion in Viaflex Container

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 get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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 belongs to the group of medicines called anti-microbials. Flagyl Infusion 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.

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:

- 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 experience:

Stomach pain, anorexia, nausea, vomiting, fever, malaise, vertigo (spinning sensation), 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, Acute Generalised Exanthematous Pustulosis) with the use of Flagyl.

Symptoms of these may include: flu-like symptoms, a painful red or purplish rash that spreads and blisters or a rash of pustules which may be accompanied by a fever. You may also have ulcers in your mouth, throat, nose or genitals. If you develop any of these you should stop taking your medicine and inform your doctor straight away (see Section 4).

Taking other medicines

Please tell your doctor 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 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 taking 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 or experience vertigo (spinning sensation), be 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

Flagyl contains Sodium

This medicine contains 310mg sodium (main component of cooking/table salt) in each 100ml. This is equivalent to 16% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 1 or more 100ml doses daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. HOW TO TAKE FLAGYL

How your medicine will be given

Your medicine will be administered to you by a doctor or nurse. The length of your course of treatment will depend on your needs and the illness being treated.

- Flagyl is administered into a vein using a drip at a rate of 5 ml/minute.
- Other antibiotics can be administered using the same minibag as Flagyl to help treat your infection.
- 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 infection you have and how bad it is.
- As soon as possible after starting your treatment with Flagyl, your doctor will suggest changing to a medicine taken by mouth.

The usual dose for adults and children is given below:

To treat bacterial infection

Adults

- You will be given 500 mg (100 ml) Flagyl every 8 hours.

Children

- Your doctor will work out how much your child should be given depending on their weight.
- The dose will be repeated 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

Adults

- You will be given 500 mg (100 ml) Flagyl shortly before your operation.
- The dose will be repeated every 8 hours.

Children

- Your doctor will work out how much your child should be given depending on their weight.
- Your child will receive Flagyl 1–2 hours before their operation.

People having kidney dialysis

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

People with liver problems

Your doctor may lower your dose or use the medicine less often.

If you take more Flagyl than you should

Your doctor will carefully calculate how much Flagyl you should get. Therefore it is unlikely your doctor or nurse will give you too much of this medicine. But, if you think that you have been given too much or too little Flagyl, tell your doctor or nurse.

If you forget to take Flagyl

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, then talk to your doctor or nurse.

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 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'.
- Your skin is red and swollen and you have a skin rash of small pustules, you may also have a fever and swelling of the face. This may be something called 'Acute Generalised Exanthematous Pustulosis'.
- 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, bruising, 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 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.
- Vertigo (spinning sensation)
- Pains in the muscles or joints.
- Fever
- Numbness, tingling, pain or a feeling of weakness in the arms or legs.
- 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 product 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, Website: www.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. Keep out of the reach and sight of children.

This is a single dose container, discard any unused solution.

You must not use the Flagyl infusion after the expiry date. This is given in two places:

- on the box.
- on the bag label.

The date is given as 'EXP' followed by the month and year. The infusion should not be given after the end 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 ingredient in your medicine is metronidazole.

Each 1 ml contains 5 mg metronidazole, thus each 100 ml bag contains 500 mg metronidazole. The solution for infusion also contains the following ingredients:

Disodium Phosphate Dodecahydrate (E139), Citric Acid Monohydrate (E330), Sodium Chloride and Water for Injections.

What Flagyl looks like and contents of the pack

Flagyl 0.5% Infusion is a clear, pale yellow sterile solution. It is available in boxes containing 100 ml Solution for Infusion viaflex bags.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

sanofi-aventis Ireland Ltd., T/A SANOFI

Citywest Business Campus,

Dublin 24.

Tel: 01 403 5600

Fax: 01 403 5687

Email: IEmedinfo@sanofi.com

Manufacturer:

Aventis Pharma,

Dagenham,

Essex, RM10 7XS,

United Kingdom

or

Baxter Healthcare S.A.,

Moneen Road,

Castlebar, Co. Mayo,
Ireland.

This leaflet was revised in July 2022