

Flagyl® S 200mg/5ml Oral Suspension

Metronidazole sanofi-aventis 200mg/5ml Oral Suspension

(metronidazole benzoate)

Your medicine is available using one of the above names, but will be referred to as Flagyl throughout this:

Patient Information Leaflet

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 further questions, please 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

The name of this medicine is Flagyl S 200mg/5ml Oral Suspension (called Flagyl in this leaflet). Flagyl contains a medicine called metronidazole benzoate. This belongs to a group of medicines called antibiotics.

It works by killing bacteria and parasites that cause infections in your body. It can be used to:

- Treat infections of the blood, brain, lung, bones, 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

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 and tell your doctor if:

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients of this medicine (listed in Section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take Flagyl if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Flagyl.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flagyl if:

- You have or have ever had a liver problem.
- You are having kidney dialysis (see section 3: 'People having kidney dialysis')
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

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

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

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of Flagyl.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk and upper extremities

The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours of treatment.

If you develop a serious rash or another of these skin symptoms, stop taking Flagyl and contact your doctor or seek medical attention immediately.

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

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured 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. This includes medicines obtained without a prescription, including herbal medicines.

This is because Flagyl can affect the way some other 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 for mental illness
- Phenobarbital or phenytoin for epilepsy
- 5 fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin – to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Flagyl.

Flagyl with food, drink and alcohol

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 heartbeat (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.
- You are breast-feeding. It is better not to take Flagyl if you are breast-feeding. This is because small amounts may pass into the mother's milk.

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 any medicine.

Driving and using machines

While 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.

Flagyl contains

- **Sucrose:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- **Methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216):** These are preservatives that are added to Flagyl to make the medicine last longer. These can cause an allergic reaction in some people.
- **Alcohol:** Flagyl contains 0.8% alcohol (ethanol) by volume; this is equivalent to 32mg alcohol per 5ml dose. At high doses this could be harmful for those suffering from alcoholism, liver disease or epilepsy.

3) How to take Flagyl

Taking your medicine

Always take this medicine exactly as your doctor or pharmacist has told you. 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 how exactly 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 suspension 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 take 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 carton and bottle 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 take a double dose to make up for a forgotten dose.

If you have any further questions on this use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

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

Stop taking Flagyl and see a doctor or go to a hospital straight away if:

- 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.
- 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 skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis. These can appear as reddish target-like spots or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Flagyl if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
- You develop a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Flagyl if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Talk to your doctor straight away if you notice the following side effects.

- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. 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: Very rare (affects less than 1 in 10 000 people)

- Fits (convulsions)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash or flushing
- Headache
- Darkening of the urine

- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

Not known (frequency cannot be estimated from the available data)

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- Unpleasant taste in the mouth
- Furred tongue
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed
- Pain in your eyes (optic neuritis)
- A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)
- Hearing impairment/hearing loss
- Ringing in the ears (tinnitus)
- You get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Flagyl

- **Keep out of the sight and reach of children.**
- Do not store above 25°C.
- Store original package in order to protect from light.
- Do not use this medicine after the expiry date shown on the bottle label and packaging.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.
- If your medicine becomes discoloured, or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Flagyl S 200mg/5ml Oral Suspension contains

Each 5ml of suspension contains the equivalent of 200mg metronidazole.

Other ingredients are: sucrose, sodium dihydrogen phosphate dihydrate (E339), aluminium magnesium silicate, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), alcohol 96%, lemon flavour, orange flavour and purified water.

What Flagyl looks like and contents of the pack

Flagyl is a white to cream coloured oral suspension with a slight yellow tinge and an odour of orange and lemon.

Flagyl is available in 100ml bottles.

PL 46420/0254 **POM**

Who makes and repackages your medicine?

Your medicine is manufactured by Unither Liquid Manufacturing, F-31770 Colomiers, France. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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