

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FLAGYL SUSPENSION 200 mg/5 mL oral suspension

Metronidazole

Contains sugar: sucrose 3 g/5 mL.

Read all of this leaflet carefully before you or your child start taking FLAGYL:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLAGYL has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What FLAGYL is and what it is used for
2. What you need to know before you take or give FLAGYL to your child
3. How to take or give 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 contains metronidazole, and it works by killing bacteria and parasites that cause infections in your body.

It can be used to:

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- treat infections caused by certain bacteria
- prevent infections after surgery.

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

2. What you need to know before you take or give FLAGYL to your child

Do not take FLAGYL or give FLAGYL to your child

- if you or your child are allergic (hypersensitive) to metronidazole or any of the other ingredients in FLAGYL. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you or your child are taking the medicine, busulfan (treatment for cancer of blood cells) (see Warnings and precautions and Other medicines and FLAGYL).
- if you are taking disulfiram (used to treat chronic alcoholism (drinking alcohol) (see Warnings and precautions and Other medicines and FLAGYL).

If you are not sure, talk to your doctor or pharmacist before taking or giving FLAGYL to your child.

Warnings and precautions

Special care should be taken with FLAGYL

- If you or your child has a family history of the following heart conditions: congenital long QT syndrome, torsades de pointes, cardiac dysrhythmias (including ventricular tachycardia).
Metronidazole, as in FLAGYL may cause prolonging of the QT interval (an irregular heart rhythm that can be seen on an electrocardiogram) when administered with medicines with the potential for prolonging the QT interval (see Other medicines and FLAGYL).
- **If you or your child have blood dyscrasias (disease of the blood with low/lack of certain blood cells) or active or chronic disease of the central (nerves of the brain and spinal cord) and peripheral (nerves outside the brain and spinal cord) nervous system.**
- If you or your child have hepatic encephalopathy (worsening of brain function that occurs when the liver is no longer able to remove toxic substances in the blood).

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients

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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. 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 (see Possible side effects).

- If you or your child receives treatment for cancer of blood cells. Co-administration with busulfan may lead to severe busulfan toxicity and death.

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 (see Possible side effects).

Some people being treated with metronidazole can experience mental health problems such as irrational thoughts, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide. These symptoms can occur even in people who have never had similar problems before. If you or others around you notice any of these side effects stop taking this medicine and seek medical advice straight away.

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Do not take alcohol beverages and medicine containing alcohol during therapy and for at least 1 to 3 days afterwards (see FLAGYL with food and drink).

Pseudomembranous colitis (infection of the colon) has been reported with the use of FLAGYL. Tell you or your child's doctor immediately if you or your child develops watery and severe diarrhoea, which may also be bloody.

If you or your child are taking FLAGYL for more than 10 days your doctor will monitor you or your child and will discontinue treatment if signs of peripheral neuropathy (disorder of the nerves which can cause weakness, tingling or numbness) or central nervous system toxicity develop. Your doctor will lower the dose of FLAGYL if you or your child suffers with severe liver disease.

FLAGYL has anti-treponemal activity (bacteria that can cause syphilis) and may mask the immunological response (the body's natural defence) seen in untreated early syphilis. If you or your child has syphilis and are receiving FLAGYL your doctor will continue testing you or your child for syphilis for an additional 4 to 8 weeks.

FLAGYL may cause darkening of urine (due to the substance that FLAGYL is broken down into in the body).

If you are not sure if any of the above applies to you or your child, talk to your doctor or pharmacist before taking FLAGYL.

Other medicines and FLAGYL

Always tell your health care provider if or your child you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- Disulfiram for the treatment of alcoholism. Taking FLAGYL with disulfiram can result in acute

Sign: 

confusion.

- Medicines used to thin the blood such as warfarin. FLAGYL intensifies the effect of warfarin and may result in uncontrolled bleeding.
- Lithium for mental illness. Blood levels of lithium may be increased by FLAGYL.
- Phenytoin or phenobarbital for epilepsy reduce the effectiveness of FLAGYL.
- 5-Fluorouracil for cancer. FLAGYL may intensify the of harmful effects of 5-fluorouracil.
- Busulfan for leukaemia (cancer of the blood cells) (see Take special care with FLAGYL).
- Medicines with the potential for prolonging the QT interval, which can be seen on an electrocardiogram (e.g. certain antipsychotics, antiarrhythmics or antibiotics).
- Ciclosporin to prevent the rejection of organs after transplant. FLAGYL may increase the blood levels of ciclosporin.
- Cimetidine for stomach ulcers may intensify the effects of FLAGYL.

Interferences with laboratory and diagnostic test

Metronidazole, as in FLAGYL, may interfere with certain types of blood test e.g. liver function, cholesterol and glucose. It may lead to false negative or an abnormally low result. Tell you or your FLAGYL if blood test are required.

FLAGYL with food, drink and alcohol

Do not drink any alcohol or medicine containing alcohol while you or your child are taking FLAGYL and for 1 to 3 days after finishing your course. Drinking alcohol whilst you are being treated with 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 breastfeeding

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby

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please consult your doctor, pharmacist or other health care provider for advice before taking FLAGYL.

Driving and using machines

While taking FLAGYL, you or your child 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 (see Possible side effects). If this happens, do not drive or use any machinery or tools.

FLAGYL contains sucrose and preservatives

- Sucrose is a type of sugar which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you or your child have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FLAGYL.
- Methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) are preservatives that are added to FLAGYL to make the medicine last longer. These can cause an allergic reaction in some people.
- FLAGYL contains 0,44 % alcohol (ethanol) by volume; this is equivalent to 17,4 mg alcohol per 5 mL dose. This small amount of alcohol will not have any noticeable effects.

3. How to take or give FLAGYL

Do not share medicines prescribed for you or your child with any other person.

Always take or give FLAGYL exactly as your doctor has instructed you or your child. 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. You should check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of FLAGYL is too strong or too weak, tell your doctor or pharmacist.

Instructions for use:

- Shake well before use.

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- Take or give FLAGYL oral suspension by mouth.
- Take or give the suspension at least 1 hour before food.
- The dose of FLAGYL will depend on your or your child's needs and the illness being treated.
- The length of your treatment will depend on the type of illness you
- or your child has and how bad it is.

If you or your child take or receive more FLAGYL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you or your child forgets to take FLAGYL

If you or your child forgets 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.

4. Possible side effects

FLAGYL can have side effects.

Not all side effects reported for FLAGYL are included in this leaflet. Should you or your child's general health worsen or if you experience any untoward effects while taking FLAGYL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking or giving your child FLAGYL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to FLAGYL. You or your child may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following

- heart rhythm problems such as
 - an irregular heart rhythm that can be seen on an electrocardiogram (QT prolongation), particularly when FLAGYL was administered with medicines with the potential for prolonging the QT interval
 - ventricular tachycardia which is a rapid heartbeat that starts in the lower chambers of the heart (ventricles) (including torsades de pointes).
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems
- liver failure
- Stevens-Johnson syndrome, toxic epidermal necrolysis. Skin rash 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 Warnings and precautions).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

Frequent side effects

- nausea (feeling sick), taste disorders, vomiting (being sick), diarrhoea, dry mouth, hairy tongue, swelling and inflammation inside of the mouth (oral mucositis), a sore or inflammation inside of the mouth (stomatitis).

Less frequent side effects

- inflammation of the colon, characterised by watery diarrhoea and stomach cramps (pseudo-membranous colitis).
- blood disorders (e.g. agranulocytosis, neutropenia, thrombocytopenia) determined by blood tests

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- psychotic disorders including confusion, irritability and hallucinations (hearing and/or seeing things that do not exist), mood disorders (such as depression)
- weakness, dizziness, drowsiness, sleeping disorders (insomnia), muscles contraction problems (ataxia), slurred or slow speech (dysarthria), abnormal walking pattern (gait impairment), uncontrolled, rapid or jerky, eye movements (nystagmus) and shaking (tremor)
- visual disorders such as double vision (diplopia) or problem with the focusing ability of the eye (myopia)
- increase in liver enzymes (AST, ALT, alkaline phosphatase) determined by liver function tests
- skin disorders such as pustular eruptions (blister-like sores), mild erythematous eruptions (feels itchy or burning) with fleeting joint pains
- myalgia (muscle pain) and arthralgia (joint pain)
- burning and pain when urinating (urethral discomfort) and darkening of the urine.

Frequency not known

- blood disorder (e.g. leucopenia) determined by blood test
- eating disorder (anorexia)
- numbness or tingling in the arms or legs and seizures (fits)
- stuffy nose (nasal congestion)
- inflammation of the pancreas (pancreatitis) and high levels of liver enzyme as determined by liver function tests
- redness of the skin (flushing)
- fever
- headache, inflammation of the meninges, a membrane covering the brain and spinal cord (aseptic meningitis), moving or spinning sensation (vertigo)
- vision disorders such as low vision, changes in colour vision, inflammation (swelling) of the eye nerve
- hearing problems or hearing loss, ringing sound in the ears (tinnitus)
- pain in the upper stomach area.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can report side effects directly to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (e-mail), <https://ae.reporting.sanofi/> (web portal) or +27 11 256 3700 (tel), or
- SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

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

5. How to store FLAGYL

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container in order to protect from light.

Do not use this medicine after the expiry date shown on the packaging.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLAGYL contains

The active substance is metronidazole (as benzoyl metronidazole).

The other ingredients are:

Ethanol, lemon flavouring, methyl hydroxybenzoate (E218), oil of orange, propyl hydroxybenzoate (E216), sodium dihydrogen phosphate, sucrose, Veegum H.V. and water.

What FLAGYL looks like and contents of the pack

Off-white, coarse, oral suspension with an orange and lemon flavour.

Sign: 

FLAGYL is packed in amber glass bottles in pack sizes of 50 mL and 100 mL suspension.

Holder of Certificate of Registration

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

South Africa

011 256 3700

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