

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flagyl™ 500mg and 1g Suppositories

Metronidazole

Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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 use Flagyl
3. How to use 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 500mg or 1g Suppositories (called Flagyl in this leaflet). Flagyl contains a medicine called metronidazole. This belongs to a group of medicines called antibiotics.

It works by killing the bacteria that cause infections in your body.

It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area and stomach
- 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 USE FLAGYL

Do not use Flagyl if:

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

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

Warnings and precautions

Talk to your doctor or pharmacist before using 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 using Flagyl. 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 after start 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 you buy without a prescription, including herbal medicines. This is because Flagyl can affect the way some other medicines work. Also some 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 rejection of organs after a transplant
- Disulfiram for alcoholism

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

Flagyl with food, drink and alcohol

Do not drink any alcohol while you are using 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

Talk to your doctor before using Flagyl if:

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- 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 use 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 this medicine.

Driving and using machines

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 machines or tools.

Tests

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

3.HOW TO USE FLAGYL

How to remove your suppositories from the pack

- | | | | | | |
|------------------------------|---------|----------------|---------|-------------------------|---------|
| 1. Tear off a section | Diagram | 2. Pull | Diagram | 3. Use the flaps | Diagram |
| containing one | | apart the | | to peel the | |
| suppository | | plastic | | plastic away | |
| | | flaps | | from the | |
| | | | | suppository | |

Using your medicine

Always use 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.

- Remember to wash your hands before and after you insert the suppository
- Flagyl suppositories are used by putting them into your back passage (rectum)
- 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

The usual dose:

- Suppositories are normally used for 3 days
- As soon as possible after starting treatment with the suppositories, your doctor will suggest changing to a medicine taken by mouth
- However, after 3 days, if your doctor wants you or your child to carry on using the suppositories, you will probably be told to use the suppositories every 12 hours.

The usual doses for adults and children using suppositories are provided below:

To treat infections

Adults and children over 10 years

- Use one 1 gram suppository, every 8 hours for 3 days. See above for dosing after 3 days

Children aged 5 - 10 years

- Use one 500mg suppository, every 8 hours for 3 days. See above for dosing after 3 days

Children aged 1 - 5 years

- Use one half of a 500mg suppository, every 8 hours for 3 days. See above for dosing

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after 3 days

Infants under 1 year old

- Use one quarter of a 500mg suppository, every 8 hours for 3 days. See above for dosing after 3 days

To prevent infections from happening after surgery

Adults and children over 10 years

- Use one 1 gram suppository 2 hours before surgery
- Repeat every 8 hours for up to 3 days. See above for dosing after 3 days

Children aged 5 - 10 years

- Use one 500mg suppository 2 hours before surgery
- Repeat every 8 hours for up to 3 days. See above for dosing after 3 days

People having kidney dialysis

Your doctor may tell you to stop using Flagyl during your dialysis and start using it again when your dialysis is finished.

People with liver problems

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

If you use more Flagyl than you should

If you have used more suppositories than you should or if you or a child swallow any suppositories, tell a doctor or go to a hospital casualty department straight away. Take the pack and any suppositories left with you. This is so that the doctors know what you have used.

If you forget to use Flagyl

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

If you have any further questions on the 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 using 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 or 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 used

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 your suppositories in a safe place out of the sight and reach of children.
- Store them below 20°C.
- Store in the original package in order to protect them from light.
- Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flagyl Suppositories contain

Each suppository contains 500mg or 1g of metronidazole as the active substance.
Other ingredients are: suppository bases E75 and W35, which are vegetable fats.

What Flagyl Suppositories look like and contents of the pack

Flagyl 500mg and 1g Suppositories are cream coloured, smooth surfaced and torpedo shaped.
They are available in blister packs of 10 suppositories.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

Tel: 0800 035 2525

Email: uk-medicalinformation@sanofi.com

Manufacturer

Haupt Pharma, Livron, France

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

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