

PATIENT INFORMATION LEAFLET

FLAGYL™ 200MG AND 400MG TABLETS

Metronidazole

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 further questions, please 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 of the side effects gets serious, or if you notice any side effects 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. Before you take Flagyl
3. How to take Flagyl
4. Possible side effects
5. How to store Flagyl
6. Further information

1. WHAT FLAGYL IS AND WHAT IT IS USED FOR

The name of this medicine is Flagyl 200mg or 400mg Tablets (called Flagyl in this leaflet). Flagyl contains a medicine called metronidazole. 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. 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 in your medicine (listed in Section 6: Further information). 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.

Take special care with Flagyl and check with your doctor or pharmacist before using your medicine 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 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.

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 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.

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 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 use Flagyl if you are breast-feeding. This is because small amounts may pass into the mother's milk.

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.

3. HOW TO TAKE FLAGYL

Taking your medicine

Always take Flagyl exactly as your doctor 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.

- Swallow the tablets whole with a drink of water
- Do not crush or chew the tablets
- Take these tablets during or just after a meal
- 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

The usual dose for adults and children is given below:

To treat bacterial infection

Adults

- The initial dose is 800mg
- After 8 hours take another dose of 400mg and repeat this dose every 8 hours

Children

- 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

Adults

- Start Taking Flagyl Tablets 24 hours before your operation
- Take 400 mg of Flagyl every 8 hours
- After the operation you may be given Flagyl either through a drip into a vein or rectally as a suppository until you are able to take tablets again

Children

- Give your child Flagyl Tablets 1-2 hours before their operation
- Your doctor will work out how much your child should take depending on their weight
- After the operation your child may be given Flagyl either through a drip into a vein or rectally as a suppository until they are able to take tablets again

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 and how often. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you how many tablets to take and how often to take them.

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 and any tablets left 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flagyl 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 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 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 your medicine in a safe place and out of the reach and sight of children.
- Store below 30° C in the original packaging (protect from light).
- Do not use this medicine after the expiry date shown on the pack.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. FURTHER INFORMATION

What Flagyl Tablets contain

Each tablet contains 200mg or 400mg of metronidazole as the active substance.

Other ingredients are: calcium hydrogen phosphate (E341), starch maize, povidone K30 (E1201) and magnesium stearate. The coating of the tablets contains: Pharmacoat 615 (E464) and Macrogol 400.

What Flagyl Tablets look like and contents of the pack

Flagyl 200mg and 400mg Tablets are white to off-white biconvex film coated tablets with 'Flagyl 200' or 'Flagyl 400' printed on one side.

Flagyl 200mg Tablets are available in aluminium/plastic blister packs of 21 tablets and HDPE bottles of 100 and 250 tablets. Flagyl 400mg Tablets are available in aluminium/plastic blister packs of 14 tablets and HDPE bottles of 100 tablets.

The Marketing Authorisation Holder is: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

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