

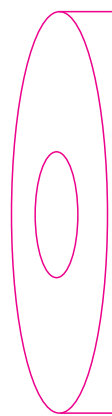


Riells Packaging Team		sanofi	
Reason for change:	New logo		
Code:	<b>897398</b>		
Description:	PRO FGL 400MG GB		
GMD Code:	832968		
Old PM Code:	869396		
Vista Folder:	4274649		
Version updated:	V1 - 26/09/2023		
Artwork Designer:	M. ROMAN		
Laetus:	773		
Fonts:	Helvetica Neue LT Std (8pt)		
Print Colors:	 Black		
Non Print Colors :	 Diecut		
Plant:	Riells		
Format:	150x315mm		
Weight:	50 grms (+/- 5%)		
Diametros:	600 (ext) / 70-76 (int)		
Spot:	3 x 8 mm		
Packaging line:	1040-2		



Dirección de Lectura

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

### FLAGYL™ 400MG TABLETS

Metronidazole

**sanofi**

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

**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 the 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 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLAGYL

##### Do not take Flagyl if:

X 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.

Tell your doctor immediately and stop taking Flagyl if you develop: stomach pain, anorexia (loss of appetite), nausea (feeling sick), vomiting (being sick), fever, malaise, fatigue, vertigo (spinning sensation), jaundice, dark urine, putty or mastic-coloured stools or itching.

##### 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.**

##### 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
- Medicines that may cause heart rhythm disturbances (so-called QT prolongation which can be seen on ECG) such as:
  - certain anti-arrhythmics (medicines for heart rhythm disorders)
  - certain antibiotics
  - medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought)

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

##### Flagyl with 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

Ask your doctor or pharmacist for advice 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.
- 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 this medicine.

##### Driving and using machines

While using Flagyl you may feel dizzy or experience vertigo (spinning sensation), confusion, hallucinations (seeing or hearing things that are not there), convulsions (fits) 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. If you are going to have a blood test, tell the doctor or nurse performing the test that you are using Flagyl. Flagyl can affect the results of some blood tests.

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

#### 3. HOW TO TAKE FLAGYL

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.

##### Taking this medicine

- 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 recommended dose is:

##### 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.

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#### To prevent infections from happening after surgery

##### Adults

- Start taking Flagyl Tablets 24 hours before your operation.
- Take 400mg 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 take 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** take a double dose to make up for a forgotten dose.

##### 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.

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 taking Flagyl and see a doctor or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

- You have an **allergic reaction**. The signs may include: swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing, an itchy, lumpy rash (hives) or nettle rash (urticaria).
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, or 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.**
- 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 any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:**

- **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)
- Vertigo (spinning sensation)
- 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
- Acute liver failure in patients with Cockayne Syndrome (see section 2 'Warnings and precautions')
- Heart rhythm disturbances (so-called QT prolongation which can be seen on ECG), particularly when Flagyl is used with other medicines that may cause heart rhythm disturbances

#### 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](http://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 this medicine out of sight and reach of children. Store below 30°C in the original packaging in order to protect from light.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

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 Tablets contain

Each tablet contains 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 400mg Tablets are white to off-white biconvex film coated tablets with 'FLAGYL 400' printed on one side. Flagyl 400mg Tablets are available in aluminium/plastic blister packs of 14 tablets and HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

##### 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](mailto:uk-medicalinformation@sanofi.com)

##### Manufacturer

Sanofi Aventis, S.A.,  
Ctra. C-35 (La Batlloria-Hostalric, Km. 63,09),  
Riells i Viabrea, 17404 Girona, SPAIN

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

**This leaflet was last revised in June 2023**  
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