

## Patient Information Leaflet

# FLAGYL™

## 500mg and 1g Suppositories (metronidazole)

Read all of this leaflet carefully before you start using this medicine.

- 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. 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 get 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 use Flagyl
3. How to use 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 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. 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 Flagyl Suppositories (see 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 use Flagyl if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using 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 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.

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 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.

**Taking Flagyl with food and drink**

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:

- You are pregnant, might become pregnant or think you may be pregnant
- 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**

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 medicines for more than 10 days.

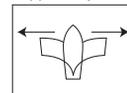
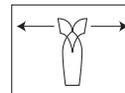
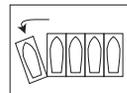
### 3. HOW TO USE FLAGYL

**How to remove your suppositories from the pack**

1. Tear off a section containing one suppository

2. Pull apart the plastic flaps

3. Use the flaps to peel the plastic away from the suppository

**Using your medicine**

Always use 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.

- 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 1g 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 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 1g 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 taken.

**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.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Flagyl 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 with blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose, and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of something called 'Stevens-Johnson Syndrome or toxic epidermal necrolysis'.

**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 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](http://www.mhra.gov.uk/yellowcard).

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 reach and sight 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 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 to protect the environment.

**6. FURTHER 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

**The Marketing Authorisation Holder is:** Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

**The Manufacturer is:** 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.

This leaflet was revised in November 2016.

"Flagyl" and "Zentiva" are registered trademarks. ©2016 Zentiva.