

Flagyl®

(flaj-ill)

Metronidazole (met-ro(h)-nide-ah-zole) 200 & 400 mg tablets; Metronidazole benzoate (met-ro(h)-nide-ah-zole benz-o(h)-ate) 200 mg/5 mL oral suspension; Metronidazole (met-ro(h)-nide-ah-zole) 500 mg suppositories

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Flagyl.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking/using Flagyl against the expected benefits they expect it will have for you.

If you have any concerns about taking/using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Flagyl is used for

Flagyl is used to treat certain infections caused by bacteria and other organisms in different parts of the body.

It is also used to prevent or treat certain infections that may occur during surgery.

Flagyl is an antibiotic that belongs to a group of medicines called nitroimidazoles.

This medicine works by killing or stopping the growth of bacteria and other organisms causing these infections.

Your doctor may have prescribed Flagyl for another reason.

Ask your doctor if you have any questions about why Flagyl has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take/use Flagyl

When you must not take/use it

Do not take/use Flagyl if you have ever had an allergic reaction to:

- **Flagyl or any other nitroimidazoles**
- **any of the ingredients listed at the end of this leaflet**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take/use Flagyl if

- **you have evidence of, or have a history of, a blood disorder**
- **you have, or have ever had, a disease of the brain, spinal cord or nerves**
- **the expiry date on the pack has passed**
If you take/use this medicine after the expiry date has passed it may have no effect at all, or worse, an entirely different effect.

- **the packaging is torn or shows signs of tampering**

If you are not sure whether to start taking/using Flagyl, talk to your doctor.

Before you start to take/use it

You must tell your doctor if you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have ever had any health problems/ medical conditions including:

- **a blood disorder**
- **disease of the brain, spinal cord or nerves**
- **liver or kidney disease**
- **an inflammatory disease of the small intestine (e.g. Crohn's disease)**
- **Cockayne syndrome**
- **you drink alcohol**
Do not drink alcohol during (and for 24 hours after stopping) treatment with Flagyl.
- **you plan to become pregnant or breastfeed**

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking/using Flagyl.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Flagyl or may affect how well it works. These include:

- warfarin or other medicines used to prevent blood clots
- Antabuse® (disulfiram), a medicine used to treat chronic alcohol dependence
- Medications containing alcohol (ethanol), e.g. some cough syrups
- some anticancer drugs, such as carmustine, cyclophosphamide, 5-fluorouracil or busulfan
- phenytoin, a drug used to treat convulsions
- phenobarbitone, a medicine for convulsions or sedation
- cimetidine, a medicine used to treat gastric reflux and ulcers
- lithium, a medicine used to treat manic depressive illness and some other types of depression
- cyclosporin, a medicine used to prevent organ transplant rejection or to treat immune responses

You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Flagyl.

How to take/use Flagyl

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take/use

The dose will vary from patient to patient. Your doctor will decide the right dose for you.

How to take Flagyl tablets

Swallow Flagyl tablets whole with a glass of water, preferably during or after a meal.

Do not chew the tablets.

This may help reduce the possibility of stomach upset.

How to take Flagyl S suspension

Flagyl S suspension should be taken at least one hour before a meal or food.

This medicine works better if taken on an empty stomach.

How to use Flagyl suppositories

Your doctor will tell you how many suppositories you need to use each day.

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use Flagyl suppositories:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep it in the foil/plastic, chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil/plastic wrapper while you are chilling it.
4. Put on a disposable glove, if desired (available from a pharmacy).
5. Remove the entire foil/plastic wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository (blunt end first) gently into your rectum (back passage).
9. Remain lying down for a few minutes so that the suppository dissolves.

10. Throw away used materials and wash your hands thoroughly.

Try not go to the toilet and open your bowels for at least an hour after inserting the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.

Use of Flagyl suppositories with condoms or diaphragms may increase the risk of rupturing the contraceptive device and hence make it ineffective.

How long to take/use it

For treating infection, Flagyl tablets and suspension are usually taken for 7 days, however, your doctor may decide to reduce or extend your treatment. Your doctor will tell you how much Flagyl to take.

Flagyl suppositories are usually used for a short time after surgery. Your doctor may replace your suppositories with oral tablets or suspension as soon as possible.

Do not stop taking your tablets or suspension or using your suppositories if you feel better.

If you do not complete the full course prescribed by your doctor, all of the bacteria/organisms causing your infection may not be killed. These bacteria/organisms may continue to grow and multiply so that your infection may not clear completely or may return.

If you forget to take/use it

If you are taking more than a single dose of Flagyl, and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take/use Flagyl, ask your pharmacist for some hints.

If you take/use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) or go to Accident and Emergency at your nearest hospital if you think that you, or anyone else, has taken/used too much Flagyl, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets or too much suspension you may experience vomiting and a feeling of disorientation.

While you are taking/using Flagyl

Things you must do

Tell your doctor immediately if:

- the symptoms of your infection do not improve or become worse
- you become pregnant
- you are about to start taking any new medicines

If you get a sore, white mouth or tongue while taking or soon after stopping Flagyl treatment, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal/yeast infection called thrush. Sometimes the use of Flagyl allows fungi/yeast to grow and the above symptoms to occur. Flagyl does not work against fungi/yeast.

If you are taking/using Flagyl for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.

If you need to have a blood test while taking/using Flagyl, tell your doctor as Flagyl may affect

the results of some laboratory tests.

Tell all doctors, dentists and pharmacists who are treating you that you are taking/using Flagyl.

Things you must not do

Do not drink alcohol or consume any medication containing alcohol while taking/using Flagyl and for at least one day after finishing treatment.

The use of alcohol may make you feel very sick, vomit, have stomach cramps, headaches and flushing.

Do not stop taking/using your medicine because you are feeling better, unless advised by your doctor.

If you do not take/use all of the medicine prescribed by your doctor, all of the bacteria/organisms causing your infection may not be killed. These bacteria/organisms may continue to grow and multiply so that your infection may not clear completely or may return.

Do not give Flagyl to anyone else, even if they have the same condition as you.

Do not use Flagyl to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Flagyl affects you.

Side Effects

Tell your doctor as soon as possible if you have any problems while taking/using Flagyl, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

As with most medications, Flagyl can sometimes cause unwanted side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- oral thrush - white, furry, sore or inflamed tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- nausea, which may be accompanied by headache, loss of appetite, and vomiting
- diarrhoea, stomach discomfort, abdominal cramping or constipation, strange taste in mouth
- convulsions, dizziness, weakness, feeling of incoordination or uncoordinated movements
- confusion, irritability, depression or sleeplessness
- skin rashes, flushing, itching
- stuffy nose, dry mouth, nasal congestion, dryness of the mouth (or vagina or vulva)
- unusual urination patterns (e.g. difficulty in passing urine, large amounts of urine, incontinence, or pus in urine)
- joint pain
- eye problems, including blurred or double vision
- hearing problems
- yellowing of the skin or eyes, which may be jaundice

If you have been on prolonged Flagyl therapy, and experience any unusual numbness of the feet or hands, stop taking/using Flagyl, and tell your doctor immediately.

Other side effects not listed above may also occur in some patients.

Tell your doctor as soon as possible if you notice any other effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking/using Flagyl

Storage

Keep Flagyl tablets/suppositories in the blister pack until it is time to take/use them.

If you take the tablets/suppositories out of the blister pack, they may not keep well.

Keep Flagyl tablets in a cool dry place where the temperature stays below 30°C.

Keep Flagyl S suspension in a cool dry place where the temperature stays below 25°C.

Keep Flagyl suppositories in a cool dry place where the temperature stays below 25°C.

Do not store Flagyl or any other medicine in the bathroom or near a sink.

Do not leave your medicine in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking/using Flagyl, or the medicines have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

There are three forms of Flagyl: Flagyl tablets, Flagyl S suspension and Flagyl suppositories.

Flagyl tablets come in two strengths:

- Flagyl 200 mg: round, white, with a breakline, marked "MTZ

200" on one side. A box contains 21 tablets.

- Flagyl 400 mg: round, white, with a breakline, marked "MTZ 400" on one side. A box contains 21 tablets

Flagyl S suspension is a creamy white to yellow liquid with an orange/lemon odour in a 100 mL bottle.

Flagyl suppositories are smooth, cream coloured and torpedo-shaped. They are packed in a blister and a carton pack contains 10 suppositories.

Ingredients

Active ingredient:

- Flagyl 200 mg - 200 mg metronidazole/tablet
- Flagyl 400 mg - 400 mg metronidazole/tablet
- Flagyl S - 200 mg - metronidazole benzoate/5 mL of liquid
- Flagyl suppositories - 500 mg metronidazole/suppository.

Inactive ingredients:

- Flagyl 200 mg & 400 mg tablets also contain calcium hydrogen phosphate, maize starch, povidone, macrogol 400, hypromellose, magnesium stearate and purified talc (400 mg only).
- Flagyl S suspension also contains monobasic sodium phosphate, aluminium magnesium silicate, sucrose, methyl and propyl hydroxybenzoate, ethanol, natural soluble lemon flavour, terpeneless orange oil, water-purified.
- Flagyl suppositories also contain hard fat.

Sponsor

Flagyl is supplied in Australia by:
sanofi-aventis australia Pty Ltd
12-24 Talavera Road

Macquarie Park NSW 2113
Australia

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Australian Registration Numbers:

Flagyl 200mg tablet: AUST R 160171

Flagyl 400mg tablet: AUST R 160174

Flagyl S suspension: AUST R 27501

Flagyl suppositories: AUST R 27499

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