

## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### **1. Why am I using Flagyl?**

Flagyl contains the active ingredient metronidazole (tablet and suppository). 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.

For more information, see Section [1. Why am I using Flagyl?](#) in the full CMI.

### **2. What should I know before I use Flagyl?**

Do not use if you have Cockayne Syndrome or have ever had an allergic reaction to Flagyl or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Flagyl?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Flagyl and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use Flagyl?**

Follow the instructions provided and use Flagyl until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Flagyl?](#) in the full CMI.

### **5. What should I know while using Flagyl?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor straight away if the symptoms of your infection do not improve or become worse, if you become</li></ul>
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	<p>pregnant or if you are about to start taking any new medicines.</p> <ul style="list-style-type: none"> <li>• Stop taking this medicine and tell your doctor straight away if you have irrational thoughts, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking Flagyl 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.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how Flagyl affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Do not drink alcohol or consume any medication containing alcohol while using Flagyl and for at least</li> </ul>

	24 hours after stopping treatment.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Flagyl tablets in a cool dry place where the temperature stays below 30°C.</li> <li>• Keep Flagyl suppositories in a cool dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using Flagyl?](#) in the full CMI.

## 6. Are there any side effects?

**Serious side effects:** Allergic reaction: 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. If you have been on prolonged Flagyl therapy, you may experience unusual numbness of the feet or hands. Posterior reversible encephalopathy syndrome (PRES) - A brain condition with symptoms such as headache, confusion, visual disturbance and seizures. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) - A serious condition with symptoms such as flu-like symptoms, rash with a fever, enlarged lymph nodes, increase in a type of white blood cell (eosinophilia) or increased levels of liver enzymes.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Flagyl® (flaj-ill)

**Active ingredients:** *Metronidazole* (met-ro(h)-nide-ah-zole) 200 & 400 mg tablets; *Metronidazole* (met-ro(h)-nide-ah-zole) 500 mg suppositories.

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Flagyl. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Flagyl.**

**Where to find information in this leaflet:**

- [1. Why am I using Flagyl?](#)
- [2. What should I know before I use Flagyl?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Flagyl?](#)
- [5. What should I know while using Flagyl?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Flagyl?

**Flagyl contains the active ingredient metronidazole (tablet and suppository).** Flagyl is an antibiotic that belongs to a group of medicines called nitroimidazoles.

**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.**

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.

## **2. What should I know before I use Flagyl?**

### **Warnings**

#### **Do not use Flagyl if:**

- you are allergic to metronidazole or any other nitroimidazoles, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- 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.
- you have Cockayne Syndrome. If you are being treated in combination with other antibiotic drugs or have Cockayne Syndrome you may experience liver failure.
- the expiry date on the pack has passed. If you 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.

### **Check with your doctor if you:**

- have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- 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
- drink alcohol. Do not drink alcohol during (and for 24 hours after stopping) treatment with Flagyl.

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



During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with Flagyl and affect how well it works. These include:**

- any medication that may cause ECG disturbances (certain anti-arrhythmics (medicines for heart rhythm disorders), certain antibiotics, psychotropic medicines)
- 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 monohydrate, 5-fluorouracil or busulfan
- phenytoin, a drug used to treat convulsions
- phenobarbital (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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Flagyl.**

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.

## **4. How do I use Flagyl?**

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this CMI.

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

## **How much to use**

- The dose will vary from patient to patient. Your doctor will decide the right dose for you.
- Follow the instructions provided when Flagyl was prescribed, including the number of days it should be taken.

## **How long to use**

- For treating infection, Flagyl tablets 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 as soon as possible.

## **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 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.

## **If you forget to use Flagyl**

**If 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 use too much Flagyl**

If you think that you have used too much Flagyl, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre  
(**by calling Australia 13 11 26**)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

## **5. What should I know while using Flagyl?**

### **Things you should do**

#### **Call your doctor straight away if:**

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

Some people being treated with metronidazole can experience mental health problems such as irrational thoughts, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide.

These symptoms can occur even in people who have never had similar problems before. If you or others around you notice any of these side effects stop taking this medicine and seek medical advice straight away.

If you experience abdominal pain, cramps, diarrhoea with possible bloody stools (which may be signs of inflammatory bowel disease).

If you experience symptoms such as headache, confusion, visual disturbance and seizures (which may be signs of a brain condition namely Posterior Reversible Encephalopathy Syndrome or PRES).

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 experience flu-like symptoms, a rash with a fever, enlarged lymph nodes and an increase in a type of white blood cell (eosinophilia), stop treatment immediately and contact your doctor or healthcare professional. Other abnormal blood test results may include (but are not limited to) increased levels of liver enzymes.

If you are 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 using Flagyl, tell your doctor as Flagyl may affect the results of some laboratory tests.

Remind any doctor, dentist or pharmacist you visit that you are using Flagyl.

## **Things you should not do**

- 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.

- Do not stop taking your tablets 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Flagyl affects you.**

While using Flagyl you may feel dizzy or experience vertigo (spinning sensation), confused, hallucinations (see or hear things that are not there), convulsions (have fits) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol may make you feel very sick, vomit, have stomach cramps, headaches and flushing.

Do not drink alcohol during (and for 24 hours after stopping) treatment with Flagyl.

## **Looking after your medicine**

- Keep Flagyl tablets/suppositories in the blister pack until it is time to use them. If you take 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 suppositories in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>General</b></p> <ul style="list-style-type: none"><li>• joint pain</li></ul> <p><b>Mouth-related</b></p> <ul style="list-style-type: none"><li>• oral thrush - white, furry, sore or inflamed tongue and mouth</li><li>• dry mouth</li></ul> <p><b>Ear-related</b></p> <ul style="list-style-type: none"><li>• hearing problems</li></ul> <p><b>Urinary disorders</b></p> <ul style="list-style-type: none"><li>• unusual urination patterns (e.g., difficulty in passing urine, large amounts of urine, incontinence, or pus in urine)</li></ul> <p><b>Respiratory related</b></p> <ul style="list-style-type: none"><li>• stuffy nose, nasal congestion</li></ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"><li>• nausea, which may be accompanied by</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<p>headache, loss of appetite, and vomiting</p> <ul style="list-style-type: none"> <li>• diarrhoea, stomach discomfort, abdominal cramping or constipation, strange taste in mouth</li> </ul> <p><b>Central nervous system-related</b></p> <ul style="list-style-type: none"> <li>• confusion, irritability, depression, or sleeplessness</li> <li>• convulsions, dizziness, weakness, feeling of incoordination or uncoordinated movements</li> <li>• vertigo (spinning sensation)</li> </ul> <p><b>Heart-related</b></p> <ul style="list-style-type: none"> <li>• Changes in electrical activity of the heart seen on an Electrocardiogram (QT prolongation) has been observed particularly when metronidazole was administered with drugs</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>with potential to prolong QT interval.</p> <p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>• skin rashes, flushing, itching</li> </ul> <p><b>Eye-related</b></p> <ul style="list-style-type: none"> <li>• eye problems, including blurred or double vision</li> </ul> <p><b>Liver-related</b></p> <ul style="list-style-type: none"> <li>• yellowing of the skin or eyes, which may be jaundice</li> </ul> <p><b>Gynecological</b></p> <ul style="list-style-type: none"> <li>• vaginal thrush - sore and itchy vagina and/or discharge</li> <li>• dryness of the vagina or vulva</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Allergic reaction. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of</li> </ul>	<p><b>Stop using Flagyl, and tell your doctor immediately</b></p>

Serious side effects	What to do
<p>the face, lips or tongue, which may cause difficulty in swallowing or breathing.</p> <ul style="list-style-type: none"> <li>• If you have been on prolonged Flagyl therapy you may experience unusual numbness of the feet or hands.</li> <li>• Posterior reversible encephalopathy syndrome (PRES) - A brain condition with symptoms such as headache, confusion, visual disturbance and seizures.</li> <li>• Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) - A serious condition with symptoms such as flu-like symptoms, rash with a fever, enlarged lymph nodes, other abnormal blood test results such as increase in a type of white blood cell (eosinophilia) or</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
increased levels of liver enzymes.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effect you experience, you can report side effects as follows:

Australia: Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

## What Flagyl contains

<b>Active ingredient (main ingredient)</b>	Flagyl 400 mg - 400 mg metronidazole/tablet  Flagyl suppositories - 500 mg metronidazole/suppository.
<b>Other ingredients (inactive ingredients)</b>	Flagyl 400 mg tablets also contain calcium hydrogen phosphate, maize starch, povidone, macrogol 400, hypromellose, magnesium stearate and purified talc.  Flagyl suppositories also contain hard fat.

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Flagyl looks like

There are three forms of Flagyl: Flagyl tablets, Flagyl S suspension and Flagyl suppositories. Flagyl S suspension is covered by a separate CMI.

Tablets are only available in Australia.

Flagyl 400 mg tablets (Aust R 160174) are round, white, with a breakline, marked "MTZ 400" on one side. A box contains 21 tablets.

Flagyl suppositories (Aust R 27499) are smooth, cream coloured and torpedo-shaped. They are packed in a blister and a carton pack contains 10 suppositories.

## **Who distributes Flagyl**

Flagyl is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australia

Freecall No: 1800 818 806

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