

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.

1. Why am I using METROGYL?

METROGYL contains the active ingredient metronidazole. METROGYL 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 METROGYL?](#) in the full CMI.

2. What should I know before I use METROGYL?

Do not use if you have ever had an allergic reaction to METROGYL 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 METROGYL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with METROGYL 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 METROGYL?

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

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

5. What should I know while using METROGYL?

Things you should do	<ul style="list-style-type: none">• Tell your doctor straight away if the symptoms of your infection do not improve or become worse, if you become pregnant or if you are about to start taking any new medicines.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking METROGYL 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how METROGYL affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol or consume any medication containing alcohol while using METROGYL and for at least 24 hours after stopping treatment.
Looking after your medicine	<ul style="list-style-type: none">• Keep METROGYL in a cool dry place where the temperature stays below 30°C. Protect from light.

For more information, see Section [5. What should I know while using METROGYL?](#) 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 METROGYL 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.

METROGYL®

Active ingredient(s): *metronidazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using METROGYL. **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 METROGYL.**

Where to find information in this leaflet:

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

1. Why am I using METROGYL?

METROGYL contains the active ingredient metronidazole. METROGYL is an antibiotic that belongs to a group of medicines called nitroimidazoles.

METROGYL 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 METROGYL for another reason.

Ask your doctor if you have any questions about why METROGYL 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 METROGYL?

Warnings

Do not use METROGYL if:

- you are allergic to metronidazole, 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 or being treated in combination with other antibiotic drugs.

- 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 METROGYL.
- have experienced sensitivity to metronidazole, or any of the other ingredients in this medicine.

Tell your doctor immediately and stop taking metronidazole if you develop:

- stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

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

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 METROGYL and affect how 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
- vecuraoonium, a medicine used is used to relax your muscles during an operation as part of the general anesthetic

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

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 METROGYL.

4. How do I use METROGYL?

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 take

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

How long to use

- For treating infection, METROGYL 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 METROGYL to take.

How to take METROGYL

Swallow METROGYL 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.

If you forget to take METROGYL

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 METROGYL, ask your pharmacist for some hints.

If you use too much METROGYL

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- 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 METROGYL?

Things you should do

Call your doctor straight away if you:

- 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 METROGYL 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 METROGYL allows fungi/yeast to grow and the above symptoms to occur. METROGYL 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 METROGYL 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 METROGYL, tell your doctor as METROGYL may affect the results of some laboratory tests.

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

Things you should not do

- Do not give METROGYL to anyone else, even if they have the same condition as you.
- Do not use METROGYL to treat any other medical complaints unless your doctor tells you to.
- Do not stop taking your tablets 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 METROGYL affects you.

While using METROGYL 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 METROGYL.

Looking after your medicine

- Keep METROGYL tablets in the bottle until it is time to use them. If you take tablets out of the bottle, they may not keep well.
- Keep METROGYL tablets in a cool dry place where the temperature stays below 30°C.

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

Store it 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>General</p> <ul style="list-style-type: none"> • joint pain <p>Mouth-related</p> <ul style="list-style-type: none"> • oral thrush - white, furry, sore or inflamed tongue and mouth • dry mouth, mouth ulcers <p>Ear-related</p> <ul style="list-style-type: none"> • hearing problems • noise such as buzzing, ringing, or whistling heard in the ear <p>Urinary disorders</p> <ul style="list-style-type: none"> • unusual urination patterns (e.g. difficulty in passing urine, large amounts of urine, incontinence, or pus in urine) <p>Respiratory related</p> <ul style="list-style-type: none"> • stuffy nose, nasal congestion <p>Gastrointestinal</p> <ul style="list-style-type: none"> • nausea, which may be accompanied by headache, indigestion, loss of appetite, and vomiting • diarrhoea, stomach discomfort, abdominal cramping or constipation, strange taste in mouth, dry mouth • pancreatitis (inflammation of the pancreas) with symptoms such as severe abdominal pain which may reach through to your back, especially associated with nausea, vomiting and fatigue <p>Central nervous system-related</p> <ul style="list-style-type: none"> • confusion, irritability, depression, or sleeplessness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> convulsions or fits, dizziness, drowsiness, weakness, feeling of incoordination or uncoordinated movements vertigo (spinning sensation) peripheral neuropathy (a disease of the peripheral nerves, symptoms of which are general weakness and numbness) tingling sensation on the skin, stiff neck associated with headache, extreme sensitivity to bright light <p>Heart-related</p> <ul style="list-style-type: none"> changes in electrical activity of the heart seen on an Electrocardiogram (QT prolongation) has been observed particularly when metronidazole was administered with drugs with potential to prolong QT interval. <p>Skin-related</p> <ul style="list-style-type: none"> skin rashes, including nettle rash, flushing, itching <p>Eye-related</p> <ul style="list-style-type: none"> eye problems, including blurred or double vision <p>Liver-related</p> <ul style="list-style-type: none"> yellowing of the skin or eyes, which may be jaundice, or darkening of urine abdominal pain, intense fatigue <p>Gynecological</p> <ul style="list-style-type: none"> vaginal thrush - sore and itchy vagina and/or discharge dryness and burning of the vagina or vulva <p>Hematotoxicity</p> <ul style="list-style-type: none"> tendency to bruise easily, notice bleeding into the skin, prolonged bleeding, bleeding from the gums or elsewhere, or you feel tired and look pale, stop taking the medicine and see your doctor 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> Allergic reaction. Some symptoms of an allergic reaction include skin rash, itching, angioedema, anaphylaxis, 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 METROGYL therapy you may experience unusual numbness of the feet or hands. acute liver failure in patients with Cockayne Syndrome. numbness, tingling, pain, or a feeling of weakness, in the arms or legs. symptoms such as headache, confusion, visual disturbance and seizures. 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 increased levels of liver enzymes. 	<p>Stop using METROGYL, and tell your doctor immediately</p>

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 effects you experience, you can report side effects to the Therapeutic Goods Administration online at 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 METROGYL contains

Active ingredient (main ingredient)	Metronidazole 200 mg or 400 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose monohydrate disodium edetate ethylcellulose sodium starch glycollate colloidal anhydrous silica guar gum

	<ul style="list-style-type: none"> • magnesium stearate • quinoline yellow aluminium lake (METROGYL 400 only)
Potential allergens	<ul style="list-style-type: none"> • galactose • sulfites • sugars as lactose

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

What METROGYL looks like

METROGYL 200 (AUST R 17654) is a 11 mm, normal convex, white tablet debossed "MZ/200" on one side and "G" on the other side. Available in pack sizes of 21 tablets or 250 tablets (hospital use only)

METROGYL 400 (AUST R 17655) is a 12.5 mm, normal convex, pale yellow tablet debossed "MZ/400" on one side and "G" on the other side. Available in pack size of 21 tablets.

Who distributes METROGYL

Arrotex Pharmaceuticals Pty Ltd
 15 – 17 Chapel Street
 Cremorne VIC 3121
www.arrotex.com.au

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