

NEW ZEALAND CONSUMER MEDICINE INFORMATION

METRONIDAMED

Metronidazole tablets, 200 mg & 400 mg

What is in this leaflet

Please read this leaflet carefully before you start taking METRONIDAMED.

This leaflet answers some common questions about METRONIDAMED.

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 METRONIDAMED against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What METRONIDAMED is used for

METRONIDAMED is used in the treatment of various infections caused by bacteria or other organisms, in different parts of the body.

It can be used to:

- prevent or treat infections that may occur during surgery.
- 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.

METRONIDAMED contains the active ingredient metronidazole. It

belongs to a group of medicines called antiprotozoals and antibacterials. This medicine works by killing or stopping the growth of bacteria and other organisms causing these infections.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine 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 METRONIDAMED

When you must not take it

Do not take METRONIDAMED if you have an allergy to:

- any medicine containing metronidazole or any other imidazoles
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take METRONIDAMED 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or

shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a blood disorder
- disease of the brain, spinal cord or nerves
- liver or kidney problems
- 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 METRONIDAMED.

Your doctor may want to take special precautions if you have any of the above conditions.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with products containing metronidazole.

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function before, during and after your treatment of metronidazole.

Tell your doctor immediately and stop taking metronidazole if you develop: stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice or dark urine.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can

discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking METRONIDAMED.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking METRONIDAMED.

Some medicines may interfere with METRONIDAMED. These include:

- anti-arrhythmic drugs (medicines used for heart rhythm disorders), certain antibiotics and psychotropic medicines. These may cause changes to electrical conductivity of the heart as shown through an Electrocardiogram.
- anticoagulant medication (used to help prevent blood clots) e.g. warfarin
- disulfiram, a medicine used to treat chronic alcohol dependence (also known as Antabuse)
- medications containing alcohol (ethanol), e.g. some cough syrups
- phenytoin, a drug used to treat convulsions
- convulsion or sedative medication e.g. phenobarbitone
- cimetidine, a medicine used to treat gastric reflux and ulcers
- lithium, a medicine used to treat depression and manic-depressive illnesses
- ciclosporin, a medicine used to prevent organ transplant rejection or to treat immune system disorders
- some anticancer drugs such as carmustine,

cyclophosphamide or 5-fluorouracil

- busulfan, a medicine used to treat leukaemia (cancer of the blood).

These medicines may be affected by METRONIDAMED or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take METRONIDAMED

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

They may differ from the information contained in this leaflet.

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

How much to take

The usual adult dose is between 200 and 800 mg, taken 2 to 3 times a day. Your doctor may increase or decrease the dose depending on your condition and how well you respond to this medicine.

The usual dose in children is less than this. The dose will be calculated by your doctor depending on the age and weight of the child.

How and when to take it

Swallow the tablets whole with a full glass of water. It is recommended that the tablets be taken during or after a meal.

Do not chew the tablets. Chewing the tablets may upset your stomach and may cause the METRONIDAMED to not work as well.

How long to take it

Continue taking your medicine until you finish the pack or until your doctor recommends that you stop taking it.

Do not stop taking the tablets because 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 have been killed. The bacteria/organisms remaining may continue to grow and multiply so that your infection may not clear completely or it may return.

If you forget to take it

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, and 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking METRONIDAMED

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 be started on any new medicine, tell your doctor and pharmacist that you are taking METRONIDAMED.

Stop taking this medicine and tell your doctor immediately if you have irrational thoughts, hallucinations, feel confused or depressed, including thoughts of self-harm or suicide.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your

doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you get a sore, white mouth or tongue while taking or soon after stopping METRONIDAMED 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 METRONIDAMED allows fungi/yeast to grow and the above symptoms to occur. METRONIDAMED does not work against fungi/yeast.

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

Things you must not do

Do not drink alcoholic drinks or consume any medication containing alcohol while taking METRONIDAMED and for at least one day (24 hours) after finishing treatment. Drinking alcohol may cause some unpleasant effects such as nausea, vomiting, stomach cramps, fast heartbeat, headaches or flushing.

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

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

Do not stop taking your tablets or lower the dose because you are feeling better unless advised by your doctor. If you do complete the full course prescribed by your doctor, not all of the bacteria/organisms causing your infection may have been killed.

These bacteria/organisms may continue to grow and multiply so that your infection may not

completely clear or may return.

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

Do not use METRONIDAMED 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 METRONIDAMED affects you.

This medicine may cause drowsiness, confusion, dizziness or convulsions in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much METRONIDAMED. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking METRONIDAMED, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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:

- changes in electrical activity of the heart seen on an Electrocardiogram (QT prolongation) have been observed particularly when metronidazole was administered with drugs with potential to prolong QT interval
- oral thrush – white furred tongue or inflamed tongue and mouth
- vaginal thrush – sore and itchy vagina and/or discharge
- problems with your eyesight such as blurred or double vision
- problems with your hearing
- skin rash, itching
- headache
- darkening of the urine, unusual urination patterns (e.g. difficulty in passing urine, large amounts of urine, incontinence, or pus in urine)
- feeling sleepy or dizzy
- irritability
- sleeplessness
- pains in the muscles or joints
- convulsions, dizziness, weakness numbness, tingling, pain or a feeling of weakness in the arms or legs
- feeling of incoordination or uncoordinated movements
- vertigo (spinning sensation)
- unpleasant taste in the mouth
- feeling sick (nausea), being sick (vomiting), upset stomach, diarrhoea, stomach discomfort or constipation
- loss of appetite
- flushing.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the skin and eyes, also called jaundice. This could be due to a liver problem.
- fits (convulsions)
- tremor, in-coordination or uncoordinated movements
- disease of the blood cells. Symptoms may include: tiredness; headaches; dizziness;

being short of breath when exercising and looking pale; frequent infections such as fever, severe chills, sore throat or mouth ulcers; bleeding or bruising more easily than normal; and nosebleeds.

- severe stomach pain which may reach through to your back (pancreatitis)
- severe blisters and bleeding of the lips, eyes, mouth, nose or genitals (Stevens Johnson Syndrome)
- blisters filled with pus.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- you get swelling of the hands, feet, ankles, face lips, tongue 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 have a serious allergic reaction to METRONIDAMED.
- changes in mood or mental health including depression, confusion or seeing or hearing things that are not there (hallucinations), thoughts of self-harm or suicide
- 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.

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

doctor immediately.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor 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 METRONIDAMED

Storage

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store METRONIDAMED or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

METRONIDAMED 200 mg tablets: White to off white colored, caplet shaped film coated tablets, debossed "200" on one side & plain on other side.

METRONIDAMED 400 mg tablets: White to off white colored, caplet shaped film coated tablets, debossed "400" on one side & plain on other side.

Ingredients

Active ingredient:

Each METRONIDAMED tablet contains either 200 mg or 400 mg of metronidazole as the active ingredient.

Inactive ingredients:

METRONIDAMED tablets also contain:

- anhydrous calcium hydrogen phosphate
- pregelatinized maize starch
- povidone
- maize starch
- crospovidone
- microcrystalline cellulose
- silica, colloidal anhydrous.
- magnesium stearate
- Hypromellose
- Polyethylene glycol 400
- Purified water

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

METRONIDAMED is supplied in New Zealand by:

Medsurge Pharma Limited
PO Box 331054

Takapuna

Auckland 0622

Telephone: 0800 788 261

Website: www.medsurgehc.com

Marketed and distributed by Medsurge Healthcare.

Date of Preparation

13 May 2024

