

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 receiving Metronidazole Medsurge?

Metronidazole Medsurge contains the active ingredient metronidazole. Metronidazole is used to treat serious infections caused by bacteria and other organisms when metronidazole cannot be given orally, prevent certain infections that may occur during surgery.

For more information, see Section 1. Why am I receiving Metronidazole Medsurge? in the full CMI.

2. What should I know before I receive Metronidazole Medsurge?

Do not use if you have ever had an allergic reaction to metronidazole or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you have or have ever had any other health problems/ medical conditions, take any other medicines, drink alcohol or ingest products containing propylene glycol, are on a low sodium diet or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I receive Metronidazole Medsurge? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Metronidazole Medsurge 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 receive Metronidazole Medsurge?

Metronidazole Medsurge is given by injection into a vein. The usual adult dose of Metronidazole Medsurge is 500mg every eight hours for the course of treatment, as decided by your doctor.

More instructions can be found in Section 4. How do I receive Metronidazole Medsurge? in the full CMI.

5. What should I know while receiving Metronidazole Medsurge?

Things you should do	 If you get a sore, white mouth or tongue while receiving or soon after stopping Metronidazole Medsurge, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do not take any diarrhoea medicine without first checking with your doctor.
Things you should not do	• Do not drink any alcohol or any alcoholic drinks while being treated with (and for one day after stopping) Metronidazole Medsurge.
Driving or using machines	 Be careful driving or operating machinery until you know how Metronidazole Medsurge affects you. This medicine may cause dizziness, confusion, hallucination (hearing or seeing strange or unusual things), convulsions ("fits") or affect how you see things. Some adverse reactions such as seizure, dizziness, optic neuropathy, may impair the ability to drive or operate machines.
Drinking alcohol	 Tell your doctor if you drink alcohol or ingest products containing propylene glycol. The use of alcohol or alcohol-containing products before, during and up to 72 hours after receiving metronidazole may make you feel sick, vomit or have stomach cramps, headaches, tachycardia or flushing.
Looking after your medicine	• Store below 30°C. Protect from light.

For more information, see Section 5. What should I know while receiving Metronidazole Medsurge? in the full CMI.

6. Are there any side <u>effects?</u>

Tell your doctor if you experience any of the following- vaginal thrush - sore and itchy vagina and/or discharge, dryness of the mouth, confusion, irritability, swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing. Other side effects not listed above may also occur in some people. For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

Metronidazole Medsurge

Active ingredient(s): Metronidazole

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I receiving Metronidazole Medsurge?
- 2. What should I know before I receive Metronidazole Medsurge?
- 3. What if I am taking other medicines?
- 4. How do I receive Metronidazole Medsurge?
- 5. What should I know while receiving Metronidazole Medsurge?
- 6. Are there any side effects?
- 7. Product details

1. Why am I receiving Metronidazole Medsurge?

Metronidazole Medsurge contains the active ingredient metronidazole. Metronidazole is an antibiotic. Metronidazole works by killing or stopping the growth of bacteria and other organisms causing these infections.

Metronidazole is used to treat

- serious infections caused by bacteria and other organisms when metronidazole cannot be given orally
- prevent certain infections that may occur during surgery.

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

Your doctor may have prescribed metronidazole for another reason.

This medicine is not addictive.

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

2. What should I know before I receive Metronidazole Medsurge?

Warnings

Do not receive Metronidazole Medsurge if:

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

- if you have or have had a blood disorder
- if you have a disease or disorder of the brain, spinal cord or nerves

Check with your doctor if you:

- are not sure whether you should be given Metronidazole Medsurge.
- have any allergies to any other medicines or any other substances such as foods, preservatives or dyes
- are on a low sodium diet.
- have or have ever had any other health problems/ medical conditions including:
 - blood disease or history of blood disease
 - disease or disorder of the brain, spinal cord or nerves
 - any heart problems
 - any kidney problems
 - any liver problems
 - Crohn's disease, an inflammatory disease of the intestines
 - Cockayne syndrome.

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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Metronidazole may affect your developing baby if you are given it during pregnancy.

You should discuss with your doctor the need for metronidazole treatment during pregnancy, and the possible risks and benefits of using metronidazole during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Metronidazole passes into breast milk and may affect your baby. The use of metronidazole is not recommended while breast- feeding. Your doctor will discuss the risks and benefits of using it when breastfeeding.

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

Contraceptives

Talk to your doctor about the need for an additional method of contraception while receiving Metronidazole Medsurge.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with metronidazole.

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 metronidazole and affect how it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you. These include:

- warfarin, or other medicines used to prevent blood clots
- disulfiram, a medicine used to treat chronic alcohol dependence
- some anticancer medicines such as carmustine, cyclophosphamide, fluorouracil and 5-fluorouracil and busulfan
- azathioprine, a medicine used to suppress the immune system
- lithium, a medicine used to treat some types of depression
- corticosteroids such as prednisone or cortisone
- cimetidine, a medicine used to treat ulcers
- phenytoin, a medicine used to treat convulsions
- phenobarbitone, a medicine to treat convulsions or for sedation
- ciclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- medicines that affect the heart rate or heart rhythm.

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

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

4. How do I receive Metronidazole Medsurge?

How much to receive / given

- Your doctor will decide what dose of metronidazole to give you and how long you will need to be given this medicine for.
- The dose will vary from patient to patient. This will depend on your age, weight, type of infection and how well your kidneys and liver are working.
- However, the usual adult dose of Metronidazole Medsurge is 500mg every eight hours for the course of treatment, as decided by your doctor.
- Your doctor will decide the right dose for you. However, depending on your condition and how you react to the medicine, your doctor may give you a different dose.
- Follow the instructions provided and use Metronidazole Medsurge until your doctor tells you to stop.

When to receive / give Metronidazole Medsurge

- 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 these instructions, ask your doctor or pharmacist for help.

How to receive Metronidazole Medsurge

- Metronidazole Medsurge is given by injection into a vein.
- It must only be given by a doctor or nurse.

If you are given too much Metronidazole Medsurge

As Metronidazole Medsurge will most likely be given to you in hospital or clinic, it is very unlikely that you will receive an overdose. However if you experience severe side effects tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

You should immediately:

- phone the Poisons Information Centre (In Australia by calling 13 11 26; In New Zealand by calling 0800 POISON (0800 764 766)), 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.

5. What should I know while receiving Metronidazole Medsurge?

Things you should do

Call your doctor straight away if:

- You become pregnant while you are being given Metronidazole Medsurge.
- the symptoms of your infection do not improve, or if they become worse.
- you are using Metronidazole Medsurge for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.
- you need to have any other blood tests, tell your doctor you are receiving Metronidazole Medsurge. Metronidazole may affect the results of some laboratory tests.
- you get a sore, white mouth or tongue while receiving or soon after stopping Metronidazole Medsurge. 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 metronidazole allows fungi / yeast to grow and the above symptoms to occur.

- Metronidazole does not work against fungi / yeast.
- you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several

weeks after Metronidazole Medsurge has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using Metronidazole Medsurge if you are about to be started on any new medicines.

Things you should not do

• Do not drink any alcohol or any alcoholic drinks while being treated with (and for one day after stopping) Metronidazole Medsurge.

The use of alcohol with metronidazole may make you feel sick, vomit or have stomach cramps, headaches or flushing

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Metronidazole Medsurge affects you.

This medicine may cause dizziness, confusion, hallucination (hearing or seeing strange or unusual things), convulsions ("fits") or affect how you see things. Some adverse reactions to metronidazole such as seizure, dizziness, optic neuropathy, may impair the ability to drive or operate machines.

Drinking alcohol

Tell your doctor if you drink alcohol or ingest products containing propylene glycol.

Do not drink alcohol or ingest products containing alcoholcontaining products before, during and up to three days after stopping treatment with Metronidazole Medsurge.

Metronidazole and alcohol or products containing propylene glycol together can cause abdominal cramps, nausea, vomiting, headaches, tachycardia and flushing.

Looking after your medicine

• Store below 30°C. Protect from light.

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 windowsills.

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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Metronidazole Medsurge.

Metronidazole helps most people with infections, but it may have unwanted side effects in a few people.

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

I and actions side offersta	What to do
Less serious side effects	What to do
 nausea, vomiting, loss of appetite abdominal pain, indigestion or discomfort constipation/diarrhoea metallic or unpleasant taste in the mouth sore red mouth ulcers or cold sores oral thrush - white, furry, sore tongue and/or mouth swollen red or sore tongue vaginal thrush - sore and itchy vagina and/or discharge dryness of the mouth, vagina or genitals loss of sex drive or painful sex joint pains nasal congestion 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

bleeding or discharge

Serious side effects	What to do
 confusion, irritability, depression, disorientation clumsiness, lack of co-ordination, problems with moving or balancing difficulty in speaking headache, stiff neck and extreme sensitivity to bright light dizziness or spinning sensation problems with sleeping fits or seizures ringing/ persistent noise in the ears (tinnitus) or other hearing problems blurred vision/double vision or other eye problems yellowing of the eyes/skin or flushing swelling or redness along the vein which is extremely tender when touched. frequent or painful urination blood or pus in the urine more or darker urine than normal loss of control of your bladder or bowels feeling of pressure around the pelvis sore back passage, sometimes with 	Tell your doctor immediately if you have any of the following as you may need urgent medical attention

Very Serious side effects

Very Serious side effects	What to do
 rash, itchiness, hives swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing tingling or numbness of the hands or feet, pins and needles or muscle weakness severe blisters and bleeding in the lips, eyes, mouth, nose and genitals signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers severe abdominal cramps or stomach cramps watery and severe diarrhoea, which may also be bloody fast, erratic heartbeats and/or fainting. 	Call your doctor straight away, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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.

Some of these side effects (changes in the liver, levels of blood cells or changes in heart rhythm) can only be found when your doctor does tests from time to time to check your progress.

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 (Australia) or the Centre for Adverse Reactions Monitoring (CARM) within the New Zealand Pharmacovigilance Centre https://nzphvc.otago.ac.nz/reporting/ (New Zealand). 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 Metronidazole Medsurge contains

Active ingredient	Metronidazole
(main ingredient)	
Other ingredients	Citric Acid Monohydrate
(inactive	Dibasic Sodium Phosphate
ingredients)	Sodium Chloride
	Water for Injections

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

What Metronidazole Medsurge looks like

Metronidazole Medsurge is a sterile, clear, almost colourless to pale yellow solution, preservative-free, isotonic formulation of metronidazole and for single use only.

Metronidazole Medsurge is available in 100mL bags. 500mg in 100 mL infusion bags (5 mg/mL).

Who distributes Metronidazole Medsurge

Medsurge Pharma Limited PO Box 331054 Takapuna Auckland 0622 Telephone: 0800 788 261 Website: <u>http://medsurgehc.com</u>

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