

METRONIDAZOLE INTRAVENOUS INFUSION

Metronidazole

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Metronidazole Intravenous Infusion. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Metronidazole Intravenous Infusion against the benefits this medicine is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What METRONIDAZOLE INTRAVENOUS INFUSION is used for

This medicine 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

This medicine is an antibiotic.

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given METRONIDAZOLE INTRAVENOUS INFUSION

When you must not be given it

Do not use Metronidazole Intravenous Infusion if:

- you have an allergy to any medicine containing metronidazole, any other medicines used to treat infections or any of the ingredients listed at the end of this leaflet

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.

- you have or have had a blood disorder
- you have a disease or disorder involving the brain, spinal cord or nerves
- you have taken disulfiram (a medicine used to treat chronic alcohol dependence) within the last two weeks
- you have ingested alcohol or products containing propylene glycol
- you have Cockayne syndrome

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given 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:

- blood disease or history of blood disease
- disease or disorder involving the brain, spinal cord or nerves
- liver disease or any liver problems
- heart disease or any heart problems
- any kidney problems
- Crohn's disease, an inflammatory disease of the intestines

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

Do not drink alcohol or ingest products containing propylene glycol during (and for three days after stopping) treatment with metronidazole.

Tell your doctor if you are on a low sodium diet.

Tell your doctor if you are pregnant or intend to become pregnant.

Metronidazole may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using metronidazole during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

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 breast-feeding.

If you have not told your doctor about any of the above, tell your doctor before you are given Metronidazole Intravenous Infusion.

Taking other medicines

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

Some medicines and Metronidazole Intravenous Infusion may interfere with each other. These include:

- disulfiram, a medicine used to treat chronic alcohol dependence
- some anticancer drugs such as carmustine, cyclophosphamide fluorouracil, 5-fluorouracil and busulfan
- warfarin or other medicines used to prevent blood clots
- phenytoin, a medicine used to treat convulsions
- phenobarbitone, a medicine to treat convulsions or for sedation
- cimetidine, a medicine used to treat ulcers
- corticosteroids such as prednisone or cortisone

- lithium, a medicine used to treat some types of depression
- azathioprine, a medicine used to suppress the immune system
- cyclosporin, a medicine used to prevent organ transplant rejection or to treat immune responses
- medicines that affect the heart rate or heart rhythm

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

Do not drink alcohol or ingest products containing propylene glycol while you are being given Metronidazole Intravenous Infusion.

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

Talk to your doctor about the need for an additional method of contraception while you are being given metronidazole.

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

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

How METRONIDAZOLE INTRAVENOUS INFUSION is given

Metronidazole Intravenous Infusion is given by injection into a vein. Metronidazole Intravenous Infusion must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive Metronidazole Intravenous Infusion. 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 Intravenous Infusion is 500mg every eight hours for the course of treatment, as decided by your doctor.

If you are given too much (overdose)

As Metronidazole Intravenous Infusion is usually given to you in hospital or clinic, it is very unlikely that you will receive an overdose. However, if you are given too much metronidazole, you may experience some of the effects listed under "Side Effects" below.

Contact Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Metronidazole Intravenous Infusion.

While you are given METRONIDAZOLE INTRAVENOUS INFUSION

Things you must do

If the symptoms of your infection do not improve or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Metronidazole Intravenous Infusion 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.

If you get any type of skin rash, tell your doctor immediately.

Metronidazole Intravenous Infusion can increase your risk of serious and sometimes fatal skin reactions. These skin reactions may appear as a skin rash that can be widespread with blisters, swelling, pain, burning, itching or peeling, often with fever.

If you get a sore white mouth or tongue while using or soon after stopping Metronidazole Intravenous Infusion, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Metronidazole Intravenous Infusion

allows fungi to grow and the above symptoms to occur. Metronidazole Intravenous Infusion does not work against fungi.

If you become pregnant while you are being treated with Metronidazole Intravenous Infusion tell your doctor immediately.

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

If you are about to start using any new medicine, tell your doctor and pharmacist that you are being treated with Metronidazole Intravenous Infusion.

If you need to have any blood tests tell your doctor you are being given Metronidazole Intravenous Infusion.

Metronidazole Intravenous Infusion may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists that you are being treated with Metronidazole Intravenous Infusion.

Things you must not do

Do not drink any alcohol or any alcoholic drinks while being treated with (and for at least three days after stopping) Metronidazole Intravenous Infusion.

The use of alcohol with Metronidazole Intravenous Infusion may make you feel sick, vomit or have stomach cramps, headaches or flushing.

Things to be careful of

Be careful driving or operating machinery until you know how Metronidazole Intravenous Infusion affects you.

This medicine may cause dizziness, confusion, hallucination (hearing or seeing strange or unusual things), convulsions (“fits”) or affect how you see things.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are using metronidazole.

Like other medicines, metronidazole can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- nausea, vomiting, loss of appetite
- constipation/diarrhoea
- abdominal pain, indigestion or discomfort
- metallic or unpleasant taste in the mouth
- swollen red or sore tongue
- sore, red mouth
- ulcers or cold sores
- oral thrush - white, furry, sore tongue and/or mouth
- 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

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

- 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
- problems with sleeping
- fits or seizures
- dizziness or spinning sensation
- ringing/ persistent noise in the ears (tinnitus) or other hearing problems
- blurred/ 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
- pain when passing urine or passing more urine than normal
- blood or pus in the urine, darker urine
- loss of control of your bladder or bowels
- feeling of pressure around the pelvis
- sore back passage, sometimes with bleeding or discharge

These may be serious side effects. You may need medical attention.

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

- sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing
- skin rash that can be widespread with blisters, swelling, pain, burning, itching or peeling, often with fever
- 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

These are 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 patients.

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.

Storage

Metronidazole Intravenous Infusion will be stored in the pharmacy or on the ward. The infusion is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product Description

What it looks like

Metronidazole Intravenous Infusion is a clear, almost colourless to pale yellow solution in a glass vial.

Ingredients

Metronidazole Intravenous Infusion contains 500 mg of metronidazole as the active ingredient.

The intravenous infusion also contains:

- citric acid
- dibasic sodium phosphate
- sodium chloride
- water for Injections

It does not contain preservatives.

Supplier

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

Australian Registration Numbers

Metronidazole intravenous infusion 500 mg in 100 mL (sterile) glass vial, available as 10 vials per pack.

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