

DBL™ Metronidazole Intravenous Infusion

Metronidazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL 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 risks and benefits. Your doctor has weighed the risks of you receiving Metronidazole against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What DBL Metronidazole Intravenous Infusion is used for

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.

Metronidazole is an antibiotic.

Metronidazole 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 metronidazole for another reason.

This medicine is not addictive.

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

Before you are given DBL Metronidazole Intravenous Infusion

When you must not be given it

You must not be given DBL Metronidazole Intravenous Infusion if:

you have an allergy to:

- **Metronidazole or any other medicines used to treat infections**
- **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 on the skin.

You must not be given this medicine if:

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

If you are not sure whether you should be given DBL Metronidazole Intravenous Infusion, contact your doctor.

Before you are given it

Tell your doctor if:

you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes, or you 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

Tell your doctor if:

you drink alcohol.

Do not drink alcohol during (and for one day after stopping) treatment with metronidazole.

you are on a low sodium diet.

you plan to become pregnant or breastfeed.

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.

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 them before you start receiving metronidazole.

Taking other medicines

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

Some medicines may interfere with metronidazole. These include:

- warfarin, a medicine used to prevent blood clots
- disulfiram, a medicine used to treat chronic alcohol dependence
- some anticancer medicines such as BiCNU (carmustine), cyclophosphamide, fluorouracil and 5-fluorouracil
- 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
- cyclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system

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

medicines. Your doctor will advise you.

Do not drink alcohol while you are being given Metronidazole Intravenous Infusion.

Metronidazole and alcohol together can cause abdominal cramps, nausea, vomiting, headaches and flushing.

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

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

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

How DBL Metronidazole Intravenous Infusion is given

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 it is given

DBL Metronidazole Intravenous Infusion is given by injection into a vein.

It must only be given by a doctor or nurse.

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 Intravenous Infusion 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.

If you are given too much(overdose)

As DBL Metronidazole Intravenous Infusion 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.

Please contact the Poisons Information Centre in Australia on 131 126 for advice on overdose management.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL Metronidazole Intravenous Infusion

Things you must do

If you become pregnant while you are being given DBL Metronidazole Intravenous Infusion, tell your doctor immediately.

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

If you are using DBL 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 need to have any other blood tests, tell your doctor you

are receiving DBL Metronidazole Intravenous Infusion.

Metronidazole may affect the results of some laboratory tests.

If you get a sore, white mouth or tongue while receiving or soon after stopping DBL Metronidazole Intravenous Infusion, 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 metronidazole allows fungi / yeast to grow and the above symptoms to occur.

Metronidazole does not work against fungi / yeast.

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

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

Things you must not do

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

The use of alcohol with metronidazole 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 DBL 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 or pharmacist as soon as possible if you do not feel well while you are using DBL Metronidazole Intravenous Infusion.

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

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.

Do not be alarmed by the following lists of 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
- 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

Tell your doctor immediately 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
- 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 bleeding or discharge

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

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

- 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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else 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.

After receiving DBL Metronidazole Intravenous Infusion

Storage

DBL 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

DBL Metronidazole Intravenous Infusion is an almost colourless to pale yellow solution in plastic minibags.

Ingredients

DBL Metronidazole Intravenous Infusion contains metronidazole as

the active ingredient. It also contains:

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

DBL Metronidazole Intravenous Infusion is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

Australian Registration Numbers

DBL Metronidazole Intravenous Infusion is available as 10 infusion bags per pack:

500mg in 100mL infusion bags
AUST R 129476

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