

DBL® Metronidazole Intravenous Infusion

Metronidazole (Met-roe-NIGH-dah-zol)

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 certain infections caused by bacteria and other organisms or to prevent certain infections that may occur during surgery.

Metronidazole is an antibiotic which belongs to a group of medicines called nitroimidazoles.

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

DBL™ Metronidazole Intravenous Infusion is used when metronidazole cannot be given orally.

Your doctor may have prescribed metronidazole for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

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 nitroimidazoles**
- **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 ever had a blood disorder**
- **you are on a low sodium diet**
- **you have a disease of the brain, spinal cord or nerves**
- **you are pregnant (unless your doctor says otherwise)**

Your doctor will discuss the risks and benefits of using metronidazole during pregnancy.

If you are a woman of child-bearing age, make sure you do not become pregnant while receiving DBL™ Metronidazole Intravenous Infusion.

You must not receive DBL™ Metronidazole Intravenous Infusion if you are breastfeeding. Like many other medicines, metronidazole passes into breast milk and may harm your baby.

You should not receive DBL™ Metronidazole Intravenous Infusion if the packaging is torn or shows signs of tampering.

Do not take DBL™ Metronidazole Intravenous Infusion if the expiry date (EXP) printed on the pack has passed.

If you are given this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should be taking 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:

- 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 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 or breastfeeding.

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 alcoholism
- some anticancer medicines such as BCNU, cyclophosphamide, fluorouracil and azathioprine
- lithium, a medicine used to treat some types of depression
- corticosteroids such as prednisone or cortisone
- cimetidine, a medicine used to treat ulcers
- phenobarbitone or phenytoin, medicines 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.

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 taking 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. Your doctor will decide the right dose for you.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

If you take too much (overdose)

As DBL™ Metronidazole Intravenous Infusion will most likely be given to you in hospital, 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 13 11 26 or in New Zealand on 0800 764 766 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 taking 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.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Metronidazole.

Things you must not do

Do not drink any alcohol or any alcoholic drinks while taking (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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking / 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
- abdominal pain or discomfort
- constipation
- loss of appetite
- metallic or unpleasant taste in the mouth
- oral thrush - white, furry, sore tongue and/or mouth
- swollen red tongue
- vaginal thrush - sore and itchy vagina and/or discharge

These are the more common side effects of metronidazole.

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
- sore red mouth
- dizziness or spinning sensation
- problems with sleeping
- fits
- vomiting or diarrhoea
- indigestion
- ulcers or cold sores

- ringing or other persistent noise in the ears
- eye problems
- yellowing of the skin or flushing
- swelling or redness along the vein which is extremely tender when touched.
- heart problems
- 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
- dryness of the vagina or genitals
- loss of sex drive or painful sex
- joint pains
- nasal congestion

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

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

These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Some of these side effects 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 anhydrous
- sodium chloride
- water for injections

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

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

500mg in 100mL infusion bags
AUST R 129476

Supplier

Australia Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 964 330
Level 3, 500 Collins Street
Melbourne, VIC 3000
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New Zealand Sponsor:

Hospira NZ Limited
Airport Oaks, Mangere 2022
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