

DBL™ Mitoxantrone Hydrochloride Injection Concentrate

Mitoxantrone (mye-toe-ZAN-trone)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Mitoxantrone Hydrochloride Injection Concentrate (mitoxantrone).

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 being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate against the benefits it is expected to have for you.

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

Keep this leaflet in a safe place. You may need to read it again.

What DBL™ Mitoxantrone Hydrochloride Injection Concentrate is used for

Mitoxantrone belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

It is used to treat some types of cancer, such as:

- breast cancer, including breast cancer which has spread to other parts of the body
- some types of leukaemia
- non-Hodgkin's lymphoma, a cancer of the lymph glands.

Mitoxantrone is thought to work by interfering with the growth of cancer cells, which slows their growth and destroys them. The growth of normal cells in other parts of your body may also be affected.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why DBL™ Mitoxantrone Hydrochloride Injection Concentrate has been prescribed for you.

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

DBL™ Mitoxantrone Hydrochloride Injection Concentrate is not recommended for use in children as there is not enough information on its effects in children.

Before you are given DBL™ Mitoxantrone Hydrochloride Injection Concentrate

When you must not be given it

You must not be given DBL™ Mitoxantrone Hydrochloride Injection Concentrate if you have an allergy to mitoxantrone, any related drugs (anthracyclines) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to mitoxantrone may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin
- dizziness or light-headedness.

You must not be given mitoxantrone if you have any of the following medical conditions:

- severe liver problems
- if you have previously been treated with mitoxantrone or an anthracycline medicine and your cardiac (heart) function has not yet returned to normal
- a reduced number of red blood cells, white blood cells, or platelets due to previous chemotherapy or radiotherapy treatment.

If you are not sure whether you should be given mitoxantrone, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

- liver problems
- any heart problems, including a heart attack
- gout
- a blood disorder with a reduced number of red blood cells, white blood cells or platelets.

Tell your doctor if you have an infection or high temperature.

Your doctor may need to treat the infection before you are given mitoxantrone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Tell your doctor if you have had drugs in the past which belong to the group called anthracyclines.

Their effects on your body may add to those caused by mitoxantrone so that you may not be able to be given it, or may need less. If you are unsure whether you have had anthracycline drugs before, ask your doctor.

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

Like most medicines used to treat cancer, mitoxantrone is not recommended to be used during pregnancy. (If there is a need to consider mitoxantrone during your pregnancy, your doctor will discuss with you the benefits and risks of using it.)

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

It is recommended that you do not breast-feed while taking Mitoxantrone, as it passes into breast milk and may cause serious side effects in your baby.

If you have not told your doctor about any of the above, tell them before you are given mitoxantrone.

Taking other medicines

Tell your doctor or pharmacist 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 mitoxantrone may interfere with each other. These include:

- some other medicines used to treat cancer
- radiation therapy or any other treatment which reduces your ability to fight infections.

These medicines may be affected by mitoxantrone, 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 or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given mitoxantrone.

How DBL™ Mitoxantrone Hydrochloride Injection Concentrate is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

Mitoxantrone may be given alone or in combination with other drugs.

Several courses of mitoxantrone therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels.

Ask your doctor or pharmacist if you want to know more about the dose of mitoxantrone you receive.

How it is given

Mitoxantrone is given as an infusion (drip) into your veins, over 3 to 5 minutes. Mitoxantrone must only be given by a doctor or nurse.

How long it is given

Mitoxantrone is usually given once every 21 days, or it may be given over 2 to 5 days, depending on your condition. This is called 'one cycle' of chemotherapy. Your doctor will decide how many of these cycles you will need. The time between each dose of mitoxantrone may change depending on the results of your blood tests.

If you take too much (overdose)

As DBL™ Mitoxantrone Hydrochloride Injection Concentrate is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Mitoxantrone Hydrochloride Injection Concentrate. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate

Things you must do

Be sure to keep all your doctor's appointments even if you are feeling ill, so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up cycles of DBL™ Mitoxantrone Hydrochloride Injection Concentrate at the appropriate times to get the best effects from your treatments.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate.

If you become pregnant while being given this medicine, tell your doctor immediately.

Mitoxantrone can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

Follow these precautions to reduce your risk of infection or bleeding:

- avoid people who have infections

- be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work
- be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters
- avoid contact sports or other situations where you may bruise or get injured
- avoid any one who has had oral polio vaccine for at least six weeks. Do not get close to them nor stay in the same room for very long. If this is not possible, you should wear a mask over your nose and mouth
- do not touch your eyes or inside your nose unless you have just washed your hands.

Things you must not do

Do not have any immunisations (vaccinations) during treatment with mitoxantrone or for some time after you have stopped treatment. If it is necessary for you to have a vaccination, discuss it with your doctor first.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Mitoxantrone Hydrochloride Injection Concentrate affects you.

As with other medicines, mitoxantrone may cause dizziness, light-headedness, tiredness or drowsiness in some people. Make sure you know how you react to mitoxantrone before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may get worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given DBL™ Mitoxantrone Hydrochloride Injection Concentrate.

Like other medicines that treat cancer, mitoxantrone may have unwanted side effects. 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.

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

You may notice a blue/green colour in your urine for up to 24 hours after you have been given mitoxantrone. You may also notice a blue/green colour around the whites of your eyes. DO NOT panic - this is quite normal and is nothing to be concerned about.

Treatment with mitoxantrone causes the breakdown of tumour cells and this may affect how your liver and kidneys work. Your doctor will arrange regular blood tests to detect any changes.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

More common side effects

- nausea or vomiting
- temporary hair loss
- mouth ulcers.

Less common side effects

- redness of skin, swelling, pain, burning or blue discolouration of the skin at the site of the injection
- diarrhoea
- loss of appetite or altered taste
- stomach pain or blood in the stool
- breathing difficulties
- fever

- tiredness or weakness
- sleepiness, confusion or anxiety
- difficulty urinating or blood in the urine
- tingling, burning or other unusual sensations anywhere on the body
- dizziness, light-headedness
- skin rash or itchy rash
- loosening or loss of fingernails
- colour changes to fingernails.

Most of the side effects of mitoxantrone are mild and do not last long.

If any of the following happen, tell your doctor or nurse immediately:

- slow or irregular heartbeat
- shortness of breath
- unusual tiredness after light exercise such as walking
- chest pain or fast heart rate
- swelling of the feet or legs.

These are serious side effects and may be signs that mitoxantrone is affecting the way your heart works. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following symptoms:

- signs of an infection (eg. fever, chills, sore throat, cough)
- soreness or ulceration of the mouth and/or anus
- unusual bleeding or bruising, (including blood in your stools or urine)
- tiredness or weakness.

These are very serious side effects and may mean the number of blood cells in your body are very low. You may need urgent medical attention or hospitalisation until the number of blood cells returns to normal.

Other side effects not listed above may occur in some patients.

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

The side effects of mitoxantrone may take some time to occur. Therefore, even after you have finished your treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

After receiving DBL™ Mitoxantrone Hydrochloride Injection Concentrate

Storage

DBL™ Mitoxantrone Hydrochloride Injection Concentrate will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25°C.

Disposal

The hospital nurse or pharmacist will dispose of any left over DBL™ Mitoxantrone Hydrochloride Injection Concentrate.

Product description

What it looks like

DBL™ Mitoxantrone Hydrochloride Injection Concentrate is a clear, dark blue solution.

Ingredients

Active ingredient:

- mitoxantrone hydrochloride

Other ingredients:

- sodium chloride
- sodium acetate trihydrate
- glacial acetic acid
- sodium metabisulfite
- water for injections

Each 10 mL glass vial of DBL™ Mitoxantrone Hydrochloride Injection Concentrate contains mitoxantrone hydrochloride equivalent to 20 mg of mitoxantrone.

DBL™ Mitoxantrone Hydrochloride Injection Concentrate does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Mitoxantrone Hydrochloride Injection Concentrate is supplied by:

- **Australian Sponsor:**
Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne 3000
Australia
- **New Zealand Sponsor:**
Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Mitoxantrone Hydrochloride Injection Concentrate is available in the following strength:
20 mg/10 mL glass vial.
AUST R 82469

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