

Mitozantrone Injection

(my-toe-ZAN-trone)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mitozantrone Injection.

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 taking Mitozantrone Injection against the benefits it is expected to have for you.

This medicine is likely to be used while you are in hospital.

If possible, please read this leaflet carefully before this medicine is given to you.

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

Keep this leaflet.

You may need to read it again.

What Mitozantrone Injection is used for

Mitozantrone (My-toe-ZAN-trone) 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.

Mitozantrone 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 Mitozantrone Injection has been prescribed for you.

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

Mitozantrone Injection will be given to you only by specially trained personnel in a hospital environment.

Mitozantrone Injection is not recommended for use in children as there is not enough information on its effects in children.

Before you are given Mitozantrone Injection

When it must not be used

You must not be given Mitozantrone Injection if you have an allergy to:

- mitozantrone
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Mitozantrone Injection may include:

- hives, itching or skin rash
- shortness of breath, wheezing
- swelling of the face, lips or tongue which may lead to

difficulty swallowing or breathing.

You must not be given Mitozantrone Injection if you have had any of the following medical conditions:

- severe liver problems
- if you have previously been treated with mitozantrone 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 mitozantrone, talk to your doctor or nurse.

Before you are given it

Your doctor and nurse need to know if you have any allergies to:

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

Your doctor and nurse need to know about all your medical conditions, especially if you have ever had any of 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 or nurse if you have an infection or high temperature.

Your doctor may need to treat the infection before you are given mitozantrone.

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

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

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

Like most medicines used to treat cancer, mitozantrone is not recommended to be used during pregnancy.

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

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

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

Taking other medicines

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

Some medicines may interfere with mitozantrone and some may cause unwanted side effects if taken while you are on mitozantrone treatment.

This is especially true if you are on any other medicines with similar side effects as mitozantrone. In some cases, two different medicines may be used together by your doctor even if an interaction might occur. In these cases, your doctor may change your dose.

If you are in doubt, check with your doctor.

How Mitozantrone Injection is given

How it is given

Mitozantrone Injection must be given only by a doctor or nurse.

This medicine is diluted and given as a slow injection into a vein. You may be given Mitozantrone Injection every 3 weeks if you are being treated for breast cancer or lymphoma, or daily for 5 days for leukaemia treatment.

How much is given

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, blood tests, how well your liver and kidneys work and whether or not other medicines are being given at the same time.

Mitozantrone may be used in combination with other anti-cancer medicines.

If you have any concerns about the dosage you receive, ask your doctor.

In Case of Overdose

As your doctor will supervise how much Mitozantrone Injection you are given, you are unlikely to have an overdose.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you may have been given too much Mitozantrone Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of a mitozantrone 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 Mitozantrone Injection

Things you MUST do:

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you become pregnant while under mitozantrone treatment, tell your doctor immediately.

Things you MUST NOT do:

Take any additional medicines without the advice of your doctor or pharmacist.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Mitozantrone Injection.

Any medicine may cause some unwanted side effects, including mitozantrone. Sometimes they are serious, most of the time they are not. Side effects can sometimes be prevented or minimised by blood and urine tests as well as taking into account your overall physical condition.

Ask your doctor or nurse 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:

The following are the more common side effects of mitozantrone and are usually mild.

Tell your doctor or nurse if you notice any of the following and they worry you.

- **Nausea and vomiting. This medicine usually causes**

nausea and vomiting. If symptoms are severe or persistent you should contact your doctor or clinic.

- Mouth ulcers, cold sores or sore red mouth
- Temporary and total hair loss, especially of the scalp. After treatment with mitozantrone has ended, normal hair growth should return
- Blue discolouration of the urine. Mitozantrone may impart a blue-green colouration to the urine for approximately 24 hours after administration.

Tell your doctor as soon as possible if:

The following list includes serious side effects that may require medical attention. Serious side effects are less common.

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

- pain, redness or swelling at the site of injection or along a vein
- diarrhoea
- stomach pain or blood in the stool
- loss of appetite or altered taste
- sleepiness, confusion or anxiety
- pins and needles
- fever, fatigue and weakness
- tiredness, headaches, dizziness and looking pale
- gout
- loosening or loss of fingernails
- colour changes to fingernails
- blue discolouration to the whites of the eyes.

Go to hospital if:

The following list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- 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
- slow or irregular heartbeat, chest pain
- unusual tiredness after light exercise such as walking
- swelling of the feet or legs
- Frequent infections such as fever, severe chills or sore throat
- bleeding or bruising more easily than normal.

Tell your doctor or nurse 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 can only be found when your doctor does tests from time to time to check your progress.

Storage

Mitozantrone Injection will be stored appropriately at the pharmacy or on the ward.

Product Description

What it looks like

Mitozantrone Injection is an ink blue solution in a plastic vial.

Mitozantrone Injection can be identified by an Australian Register Number, which is found on the packaging:

AUST R 74509 Mitozantrone Injection 10mg in 5mL (sterile) Plastic Vial (single vial).

AUST R 74510 Mitozantrone Injection 20mg in 10mL (sterile) Plastic Vial (single vial).

AUST R 74511 Mitozantrone Injection 25mg in 12.5mL (sterile) Plastic Vial (single vial).

AUST R 74512 Mitozantrone Injection 30mg in 15mL (sterile) Plastic Vial (single vial).

Ingredients

Mitozantrone Injection contains the active ingredient Mitozantrone Hydrochloride 2mg/mL

The inactive ingredients are:

- Sodium Chloride BP
- Disodium Edetate BP
- Acetic Acid
- Sodium Acetate in Water for Injections BP.

Supplier

Mitozantrone Injection is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia
Toll Free number: 1800 675 229

Manufactured by:

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
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