

MITOZANTRONE EBewe

Mitozantrone (My-toe-ZAN-trone).

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mitozantrone Ebewe.

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 mitozantrone 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 Mitozantrone Ebewe is used for

Mitozantrone (My-toe-ZANtrone) belongs to the 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.

Mitozantrone may also be used to treat other conditions as determined by your doctor.

Ask your doctor if you have any questions about why Mitozantrone Ebewe has been prescribed for you.

It is important to remember that Mitozantrone Ebewe is a **PRESCRIPTION ONLY MEDICINE**.

Mitozantrone Ebewe will only be given to you 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 Ebewe

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 may include

- rashes, itching and redness of the skin
- shortness of breath, wheezing
- swelling of the tongue, lips or face which may lead to difficulty swallowing or breathing.

You have or have had any other medical conditions, especially the following:

- gout
- 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

This medicine is not recommended for intrathecal use.

If you are not sure whether any of these apply to you, check with your doctor or pharmacist.

Before you are given mitozantrone

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 breastfeed.

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.

You are 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 Ebewe is given

How it is given

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

This medicine is diluted and given as a slow injection into a vein. You may be given Mitozantrone Ebewe 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 drugs.

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

In Case of Overdose

Your doctor will decide what dose of Mitozantrone Ebewe you need, and this will be administered in the clinic or hospital under close supervision from nursing and medical staff. The risk of overdose in these circumstances is low. In the event of overdose occurring, your doctor will decide on the necessary treatment.

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 Ebewe

Things you MUST do:

- Be sure to keep all of your doctors appointments so that your progress can be checked.
- 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 Ebewe.

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 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 immediately if you notice any of the following:

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

- pain, redness or swelling at the site of injection or along a vein
- diarrhoea
- Stomach pain or dark, tarry stools or stools containing blood,
- loss of appetite or altered taste.
- sleepiness, confusion or anxiety
- pins and needles
- tiredness, headaches, dizziness or looking pale
- gout
- loosening or loss of fingernails
- difficult or laboured breathing.
- fever, fatigue and weakness.
- rash on the skin or colour changes to the nails.
- blue discolouration to the whites of the eyes

Tell your doctor if:

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

Tell your doctor 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.
- Anaemia.
- Loss of appetite.
- 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.

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.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor or nurse. Some side effects may only be seen by your doctor.

Storage:

Mitozantrone Ebewe will be stored appropriately at the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

Product Description

What it looks like

Mitozantrone Ebewe is clear blue solution in a glass vial.

Active Ingredients:

Each mL contains 2 mg of mitozantrone (equivalent to 2.328 mg of mitozantrone hydrochloride)

20mg/10mL:

Each 10 mL vial contains 20 mg of mitozantrone (equivalent to 23.284 mg of mitozantrone hydrochloride)

10mg/5mL:

Each 5 mL vial contains 10 mg of mitozantrone (equivalent to 11.642 mg of mitozantrone hydrochloride)

Other ingredients:

- sodium chloride,
- sodium sulphate,
- hydrochloric acid,
- acetic acid,
- sodium acetate,
- water for injections and
- nitrogen

Vial stopper is not made with natural rubber latex.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Australian Register Numbers

AUST R 132319

Mitozantrone Ebewe 10mg in 5mL glass vial (single vial).

AUST R 132327

Mitozantrone Ebewe 20mg in 10mL glass vial (single vial).

This leaflet was prepared in October 2018.

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