

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.

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.

What Mitozantrone Ebewe is used for

Mitozantrone (My-toe-ZAN-trone) belongs to the group of medicines called antineoplastics. It is typically used to treat cancer of the breast, but may also be used for the treatment of non-Hodgkin's Lymphoma and leukaemia. 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.

Before you are given Mitozantrone Ebewe

This medicine should not be given to you if:

You are pregnant or intend to become pregnant.

This medicine is not recommended during pregnancy.

You are breast-feeding or plan to breast feed.

This medicine is not recommended while you are breast-feeding.

You have an allergic or unusual reaction previously to mitozantrone or 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 and swelling of the tongue or face.

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

Before you are given mitozantrone, tell your doctor if:

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

- gout
- anaemia
- any type of liver condition
- any type of heart condition

You are taking other medicines.

Tell your doctor 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.

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 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 are uncommon or rare effects. You may need urgent medical attention.

- pain or redness at the place of injection.
- dark, tarry stools or stools containing blood, diarrhoea, abdominal pain or altered taste.
- 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

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.

- 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.

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

Storage

Mitoxantrone 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 an ink blue solution in a glass vial.

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

AUST R 132319
Mitozantrone Ebewe 10mg in 5mL glass vial (single vial).

AUST R 132327
Mitozantrone Ebewe 20mg in 10mL glass vial (single vial).

Ingredients

Mitozantrone Ebewe contains mitozantrone hydrochloride 2mg/mL, sodium chloride, sodium sulphate, hydrochloric acid, acetic acid and sodium acetate in water for injections.

Manufacturer

Mitozantrone Ebewe is made
by:
EBEWE Pharma Ges.m.b.H.
Nfg. KG
A-4866 Unterach
Austria

Sponsor

Mitozantrone Ebewe is
distributed in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
Level 2, 19 Harris St
Pyrmont NSW 2009
Australia
Tel: 1800 634 500

Mitozantrone Ebewe is
distributed in New Zealand by:
Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149Tel: 0800 354
335

This leaflet was prepared in 09
December 2014.