

# Mitozantrone Ebewe®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given Mitozantrone Ebewe?

Mitozantrone Ebewe contains the active ingredient mitozantrone. Mitozantrone Ebewe is used to treat various types of cancer.

For more information, see Section [1. Why am I being given Mitozantrone Ebewe?](#) in the full CMI.

### 2. What should I know before I am given Mitozantrone Ebewe?

Do not use if you have ever had an allergic reaction to mitozantrone or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Mitozantrone Ebewe?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Mitozantrone Ebewe and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How am I given Mitozantrone Ebewe?

- Your doctor or trained nurse will give Mitozantrone Ebewe by an infusion (drip) into a vein (intravenously). The infusion usually takes 15 to 30 minutes. You may need several infusions at regular intervals. These are known as 'cycles of chemotherapy'.

More instructions can be found in Section [4. How am I given Mitozantrone Ebewe?](#) in the full CMI.

### 5. What should I know while being given Mitozantrone Ebewe?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Be aware that your urine may turn a blue-green colour after your dose of Mitozantrone Ebewe</li><li>Keep all your doctor's appointments to get the best effects from treatment, and so your progress can be checked.</li><li>For men and women of childbearing age: Use a reliable form of birth control while you are being treated with Mitozantrone Ebewe and for at least 6 months after your treatment has stopped.</li><li>Call your doctor straight away if you become pregnant while you are receiving Mitozantrone Ebewe or if you experience any pain during the injection of Mitozantrone Ebewe</li><li>Remind any doctor, dentist, nurse or pharmacist you visit that you are receiving Mitozantrone Ebewe.</li><li>Take precautions to minimise the risk of infections and bleeding.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how Mitozantrone Ebewe affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Avoid drinking alcohol while you are receiving Mitozantrone Ebewe.</li></ul>

For more information, see Section [5. What should I know while being given Mitozantrone Ebewe?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. You may experience non-serious and serious side effects, including cardiac failure, while on Mitozantrone Ebewe. Most common side effects include nausea, vomiting, painful mouth ulcers, difficulty swallowing, fatigue, pale skin, bruising, fever, tiny red, purple or brown spots on skin, hair loss and blue-green urine.

Speak to your doctor, nurse or pharmacist if you experience any symptoms.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Mitozantrone Ebewe®

Active ingredient(s): mitozantrone (as hydrochloride)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Mitozantrone Ebewe. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mitozantrone Ebewe.**

Where to find information in this leaflet:

- [1. Why am I being given Mitozantrone Ebewe?](#)
- [2. What should I know before I am given Mitozantrone Ebewe?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I being given Mitozantrone Ebewe?](#)
- [5. What should I know while being given Mitozantrone Ebewe?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given Mitozantrone Ebewe?

Mitozantrone Ebewe contains the active ingredient **mitozantrone (as hydrochloride)**. Mitozantrone is a type of chemotherapy medicine. It belongs to a group of medicines called antineoplastic or cytotoxic medicines.

Mitozantrone Ebewe is used to treat various types of cancer, including:

- **breast cancer**
- **non-Hodgkin's lymphoma (a cancer of the lymph glands)**
- **adult acute non-lymphocytic leukaemia (ANLL)**
- **advanced chronic myeloid leukaemia (CML)**

Mitozantrone Ebewe works by stopping cancer cells from growing and multiplying. It may be used in combination with other medicines to treat cancer.

## 2. What should I know before I am given Mitozantrone Ebewe?

### Warnings

**Do not use Mitozantrone Ebewe if:**

- you are allergic to mitozantrone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some 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

**Do not take this medicine if you have or have any of the following medical conditions:**

- severe liver problems
- a condition of the blood with a reduced number of red or white blood cells or platelets because of previous chemotherapy or radiotherapy.
- You have already received a long-term dose of Mitozantrone Ebewe or similar medicines such as doxorubicin, idarubicin, epirubicin, or daunorubicin, and you have heart problems

**This medicine is not recommended for intrathecal use.**

**Check with your doctor if you:**

- have any other medical conditions, including:
  - liver problems
  - kidney problems
  - heart problems, including a heart attack
  - gout, a disease with painful, swollen joints caused by high uric acid levels
  - a blood disorder with a reduced number of red blood cells, white blood cells or platelets
  - lowered immunity due to treatment with certain medicines (corticosteroids, cyclosporine, medicines used to treat cancer) or radiation treatment
- take any medicines for any other condition
- in the past, have taken medicines for cancer, or had radiation therapy
- have an infection or high temperature.

If you have an infection, your doctor may decide to delay your treatment until your infection is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not have Mitozantrone Ebewe if you are pregnant or intend to become pregnant.**

Like most medicines used to treat cancer, mitozantrone is not recommended for use in pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant, to discuss the risks and benefits. See also 'People of childbearing age'.

**Do not breastfeed while receiving Mitozantrone Ebewe.**

Mitozantrone Ebewe passes into the breast milk and may affect the breast-fed baby.

Tell your doctor or nurse if you are breastfeeding or intend to breastfeed.

## People of childbearing age

**Use a reliable form of birth control while you are being treated with Mitozantrone Ebewe and for at least 6 months after your treatment has stopped.**

Mitozantrone Ebewe may cause birth defects if either males or females are being treated with it at the time of conception.

## Use in children

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

## 3. What if I am taking other medicines?

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

**Some medicines and Mitozantrone Ebewe may interfere with each other. These medicines may be affected by Mitozantrone Ebewe or may affect how it works. These include:**

- doxorubicin, idarubicin, epirubicin, or daunorubicin also known as 'anthracyclines'
- other chemotherapy medicines including cyclophosphamide, fluorouracil, vincristine, vinblastine, bleomycin, methotrexate, and cytosine arabinoside
- cyclosporine, a medicine used in organ transplants
- vaccines, especially live vaccines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mitozantrone Ebewe.**

## 4. How am I given Mitozantrone Ebewe?

### How much 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 is it 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.**

## If you are given too much Mitozantrone Ebewe

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.

If you think that you have been given too much Mitozantrone Ebewe, you may need urgent medical attention.

### You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while being given Mitozantrone Ebewe?

### Things you should do

- Be aware that your urine may turn a blue-green colour after your dose of Mitozantrone Ebewe.

You may also notice a blue-green tinge in the whites of your eyes. These are normal effects of Mitozantrone Ebewe and will disappear after 1 or 2 days.

- Keep all your doctor's appointments to get the best effects from treatment, and so your progress can be checked.

It is important to have your follow-up doses at the appropriate times to get the best treatment outcomes.

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

- Remind any doctor, dentist, nurse or pharmacist you visit that you are using Mitozantrone Ebewe.
- For men and women of childbearing age: Use a reliable form of birth control while you are being treated with Mitozantrone Ebewe and for at least 6 months after your treatment has stopped.

Mitozantrone Ebewe may cause birth defects if either males or females are being treated with it at the time of conception.

### Tell your doctor straight away if you:

- become pregnant while receiving Mitozantrone Ebewe
- experience any pain during the injection of Mitozantrone Ebewe.

## Reducing the risk of infection and bleeding

Mitozantrone Ebewe 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.

To reduce the risk of infection and bleeding, follow these precautions:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- 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.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Mitozantrone Ebewe affects you.**

As with many other medicines, Mitozantrone Ebewe may cause tiredness in some people.

## Drinking alcohol

**Avoid drinking alcohol while you are on Mitozantrone Ebewe.**

Alcohol may worsen some side effects of Mitozantrone Ebewe, such as tiredness.

## Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Gut related:</b></p> <ul style="list-style-type: none"><li>• nausea</li><li>• vomiting</li><li>• mouth ulcers</li><li>• diarrhoea</li><li>• decreased appetite</li><li>• constipation</li><li>• stomach pain</li><li>• altered sense of taste</li></ul> <p><b>Hair and skin:</b></p> <ul style="list-style-type: none"><li>• unusual hair loss or thinning</li><li>• darkening of nails or skin (pigmentation)</li><li>• rash</li></ul> <p><b>Others:</b></p> <ul style="list-style-type: none"><li>• blue-green colouration of urine, or the whites of the eyes</li><li>• weakness or sleepiness</li><li>• feeling anxious</li><li>• changes in sensation (numbness or tingling in any part of your body)</li><li>• no menstrual bleeding.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Blood count related:</b></p> <ul style="list-style-type: none"><li>• tiredness, headaches, short of breath when exercising, dizziness &amp; looking pale</li><li>• bleeding or bruising more easily than normal, nosebleeds</li></ul> <p><b>Infection-related</b></p> <ul style="list-style-type: none"><li>• signs of sepsis (an extreme immune response to infection) which may include:<ul style="list-style-type: none"><li>• fever or chills</li><li>• confusion</li><li>• difficulty breathing</li><li>• convulsions</li></ul></li></ul> <p><b>Heart or lung related:</b></p> <ul style="list-style-type: none"><li>• fatigue</li><li>• chest pain</li><li>• palpitations</li><li>• altered heartbeat</li><li>• difficulty in breathing</li><li>• dry cough</li><li>• swelling and weight gain from fluid in your ankles, lower legs, or belly</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<p><b>Injection related:</b></p> <ul style="list-style-type: none"> <li>• pain, redness, swelling, burning near the injection site or along the infusion vein</li> <li>• blue colour of skin near the injection site</li> </ul> <p><b>Allergic reaction related:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest</li> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• rash, itching, hives or flushed, red skin</li> <li>• dizziness or light-headedness</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>• blood in urine or stools</li> <li>• severe stomach pain or swelling</li> <li>• yellowing of the whites of the eyes, and yellowing of the skin.</li> </ul>	
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The benefits and side effects of Mitozantrone Ebewe may take some time to occur. Therefore, even after you have finished your Mitozantrone Ebewe treatment, you should tell your doctor immediately if you notice any of the side effects listed in this section.

**In some cases, patients have developed other cancers, several years after treatment with mitozantrone.**

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Mitozantrone Ebewe contains

<b>Active ingredient (main ingredient)</b>	mitozantrone
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• sodium chloride</li> <li>• sodium sulphate</li> <li>• hydrochloric acid</li> </ul>

	<ul style="list-style-type: none"> <li>• acetic acid</li> <li>• sodium acetate</li> <li>• water for injections</li> <li>• nitrogen</li> </ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

Vial stopper is not made with natural rubber latex.

### What Mitozantrone Ebewe looks like

Mitozantrone Ebewe 10 mg/ 5 mL – sterile, clear, blue, aqueous, isotonic solution for injection (Aust R 132319).

Mitozantrone Ebewe 20 mg/ 10 mL – sterile, clear, blue, aqueous, isotonic solution for injection (Aust R 132327).

Each strength comes as a single vial.

### Who distributes Mitozantrone Ebewe

Mitozantrone Ebewe is distributed in Australia by:

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

Mitozantrone Ebewe is distributed in New Zealand by:

Sandoz New Zealand Limited  
12 Madden Street  
Auckland 1010  
New Zealand  
Tel 0800 726 369

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