

# Epirubicin Ebewe

Epirubicin (*epi-ROO-bi-sin*)

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Epirubicin Ebewe. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Epirubicin Ebewe against the benefits they expect it will 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. In some cases this leaflet may be given to you after the medicine has been used.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

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

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### What Epirubicin Ebewe is used for

This medicine is used to treat the following types of cancer:

- breast cancer
- gastric (stomach) cancer
- ovarian cancer
- small cell lung cancer

- lymphoma (non-Hodgkin's lymphoma), a cancer of the lymph glands
- soft tissue cancer
- bladder cancer.

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. Epirubicin Ebewe is an anthracycline-type of chemotherapy medicine. This medicine works by killing cancer cells and stopping cancer cells from growing and multiplying.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

Epirubicin Ebewe may be used alone or in combination with other medicines to treat cancer.

This medicine is not addictive.

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

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### Before you are given Epirubicin Ebewe

***When you must not be given it***

You must not be given Epirubicin Ebewe if you have an allergy to:

- any medicine containing Epirubicin

- any of the ingredients listed at the end of this leaflet
- any other similar medicines, including anthracyclines.

Some of the 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.

**Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Like most cytotoxic medicines, Epirubicin Ebewe is not recommended for use during pregnancy. If there is any need to consider Epirubicin Ebewe during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

**Women being treated with Epirubicin Ebewe must use effective contraceptive methods during treatment with Epirubicin Ebewe and at least 6.5 months after treatment.**

**Males: tell your doctor if your partner intends to become pregnant while you are being given Epirubicin Ebewe or shortly after you have stopped treatment with Epirubicin Ebewe.**

**Men being treated with Epirubicin Ebewe must use effective contraceptive methods during treatment and for at least 3.5 months after treatment.**

Epirubicin Ebewe may cause birth defects if either the male or female is using it at the time of conception.

**Do not breast-feed while being treated with this medicine.**

Epirubicin Ebewe may pass into breast milk and there is a possibility that your baby may be affected.

**Do not use the medicine for injection into a vein if you have:**

- a low number of red blood cells, white blood cells or platelets in your blood
- sore, red mouth from previous treatment or radiation therapy
- an infection
- severe liver problems
- heart problems or have ever had heart problems
- already received the highest dose allowed for medicines such as mitozantrone, mitomycin C, doxorubicin or daunorubicin.

**Do not use the medicine for injection into the bladder if you have:**

- cancer that has gone into the bladder wall
- kidney or urinary tract infection
- swollen or inflamed bladder
- problems with a catheter (a tube in your bladder)

- blood in the urine.

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

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

**You must not be given this medicine if you have already received the maximum, long-term dose of Epirubicin Ebewe or another anthracycline medicine.**

**If you are not sure whether you should be given this medicine, talk to your doctor.**

**Epirubicin Ebewe is known to be very powerful at reducing the body's ability to make new red and white blood cells. Regular blood tests may be required**

**It is also important to inform your doctor if you have any infection or fever before, during or after therapy with Epirubicin Ebewe, as the drug will lower your ability to fight infection.**

**Drugs such as Epirubicin Ebewe are also known to affect the heart, particularly after a long period of treatment. Your doctor will monitor your heart regularly before, during and after treatment**

***Before you are given it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- heart problems or have ever had heart problems
- kidney problems
- liver problems any blood disorder with a reduced number of red or white blood cells and/or reduced number of platelets
- high uric acid levels in your blood which may cause gout
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)
- lowered immunity due to diseases including HIV/AIDS.

**You must tell your doctor if you:**

- have had radiation therapy previously or are having radiation therapy
- have been treated previously with medicines to treat cancer
- are going to be vaccinated (have an injection to prevent a certain disease)
- are planning to have children.

Epirubicin may decrease the fertility of men and women. You should seek advice from your doctor on preserving fertility before starting treatment with Epirubicin Ebewe.

If you have not told your doctor about any of the above, tell him/her before you are given Epirubicin Ebewe.

## ***Taking other medicines***

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

**Some medicines and Epirubicin Ebewe may interfere with each other.**

**These include:**

- medicines used to treat cancer such as:
  - 5-fluorouracil
  - cyclophosphamide
  - cisplatin
  - paclitaxel
  - docetaxel
  - trastuzumab
    - other medicines to treat cancer.
- medicines used to treat angina or high blood pressure such as:
  - nifedipine
  - verapamil
  - diltiazem
  - felodipine
  - amlodipine
  - lercanidipine
    - propranolol.
- cimetidine (a medicine used to treat heartburn or stomach ulcers)
- other medicines that may affect how well your liver works
- some vaccines (ask your doctor).

These medicines may be affected by Epirubicin Ebewe, 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 and pharmacist have more information on medicines to be careful with or avoid while you are being treated with this medicine.

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## **How Epirubicin Ebewe is given**

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### ***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, liver function, kidney function and other chemotherapy medicines you are being given.

Epirubicin Ebewe may be given alone or in combination with other drugs.

Several courses of Epirubicin Ebewe 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 and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of Epirubicin Ebewe you receive.

### ***How it is given***

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

This medicine is usually given as a slow injection into a vein.

This medicine might also be infused into the bladder through a tube (called a catheter).

### ***How long it is given***

Epirubicin Ebewe may be given every 3 to 4 weeks, sometimes in combination with other medicines. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need, and the length between cycles.

### ***If you are given too much (overdose)***

**As Epirubicin Ebewe is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given Epirubicin Ebewe, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.**

You may need urgent medical attention.

Symptoms of an Epirubicin Ebewe overdose may include bleeding and infections due to a very low level of blood cells, and heart problems.

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## **While you are being given Epirubicin Ebewe**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Epirubicin Ebewe.**

**Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while being given this medicine, or soon after, tell your doctor immediately.**

**Keep all your doctor's appointments 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 to detect any unwanted side effects.

**Keep follow up appointments with your doctor.**

It is important to have your follow-up doses of Epirubicin Ebewe at the appropriate times to get the best effects from your treatments.

**You will be asked to not drink fluids for 12 hours before treatment if this medicine is to be infused into the bladder. This is to reduce dilution of the medicine by the urine.**

Epirubicin 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. The following precautions should be taken to reduce your risk of infection or bleeding:

- 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.

Your body breaks down Epirubicin Ebewe and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.

- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

***Things to be careful of***

**Be careful when driving or operating machinery until you know how Epirubicin Ebewe affects you.**

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness or light-headedness may be worse.

**Try to stay out of direct sunlight after treatment with Epirubicin Ebewe.**

Epirubicin Ebewe can increase your sensitivity to the sun.

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**Side effects**

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**Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with Epirubicin Ebewe.**

Like other medicines that treat cancer, Epirubicin Ebewe may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting 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.**

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

- nausea (feeling sick) or vomiting
- diarrhoea
- sore mouth or tongue, mouth ulcers, redness of mouth, sore vagina or rectum
- redness of the skin or vein at the site of the injection
- hair loss, beard stops growing
- dehydration (thirsty, dry mouth, dry skin, loss of body fluid)
- sore oesophagus (food pipe), pain on swallowing or difficulty swallowing
- stomach pain or burning feeling in stomach
- skin rash, itchy skin, hives, sensitive skin, blisters
- change in colour of skin or nails
- increased sensitivity to the sun

- itchy eye, crusty eyelid, sore red eye, blurred vision, conjunctivitis
- loss of appetite
- absence of menstrual bleeding (temporary loss of periods)
- hot flushes
- weakness, tiredness, dizziness, confusion, depression
- tingling or numbness of hands or feet; pins and needles
- gouturine discolouration (do not be alarmed if Epirubicin Ebewe colours your urine red for 1-2 days after treatment).

The above list includes the more common side effects of this medicine.

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

- stinging, swelling or pain at the site of injection
- flushing of face while the injection is being given
- an infection or chills, fever, sore throat, swollen glands, shock
- heart problems, fast or irregular heartbeat, shortness of breath
- swelling of ankles, feet, legs or hands
- bleeding or bruising under the skin
- cough, difficulty breathing, chest pain, coughing up blood
- swelling, pain, tenderness and
- redness of the leg.

The above list includes serious side effects which may require medical attention.

**If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:**

- any signs of infection such as fever, chills, sore throat or cough
- unusual bleeding or bruising (such as dark stools, blood in urine)
- irregular heart beat or symptoms of heart failure (such as shortness of breath, swelling of the ankles)
- signs of an allergic reaction (such as those listed at the start of the leaflet)

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

**If Epirubicin Ebewe is being injected into the bladder, tell your doctor or pharmacist if you notice any of the following:**

- stomach pain
- blood in the urine
- pain on passing urine
- frequent urination or difficulty urinating.

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

Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

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## After being given Epirubicin Ebewe

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**Tell your doctor immediately if you notice any of the following side effects, even if they occur several months or years after stopping treatment with Epirubicin Ebewe:**

- heart problems, fast or irregular heartbeat, shortness of breath
- swelling of ankles, feet, legs or hands, swelling in the stomach
- fever or other signs of infection.

Leukaemia may occur after treatment with Epirubicin Ebewe and other medicines to treat cancer. It is rare.

### Storage

Epirubicin Ebewe injection will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator where the temperature stays between 2 and 8 °C and protected from light. After use, any unused portion of the vial will be discarded.

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## Product description

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### What it looks like

Epirubicin Ebewe Hydrochloride Injection is a clear, red solution. It is supplied in vials as single packs.

### Ingredients

Active ingredient:

epirubicin hydrochloride

Other ingredients: sodium chloride, water for injections and hydrochloric acid in order to adjust the pH

Epirubicin Ebewe does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### Manufacturer

Epirubicin Ebewe is made by:

Ebewe Pharmaceuticals Ltd  
A-4866  
Unterach  
Austria, Europe

### Sponsor

Epirubicin Ebewe is distributed in Australia by:

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

Epirubicin Ebewe is available in the following strengths:

- 10mg/5mL: AUST R 131943
- 50mg/25mL: AUST R 131950
- 100mg/50mL: AUST R 131951
- 200mg/100mL: AUST R 131952

Epirubicin 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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