

Epirube

Epirubicin Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor.

All medicines have risks and benefits.

Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

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

Keep this leaflet with this medicine.

You may need to read it again.

What EPIRUBE is used for

EPIRUBE is used in the treatment of various types of cancer. It may be used alone or with other medicines.

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

Your doctor may have prescribed it for another purpose.

EPIRUBE is only available with a doctor's prescription.

It is not addictive.

Before you are given Epirube

When you must not be given it

Do not use EPIRUBE if you have ever had an allergic reaction to epirubicin (the active ingredient in EPIRUBE), other medicines to treat cancer or any of the ingredients listed at the end of this leaflet.

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 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
- contracted bladder

- large volume of residual urine
- problems with a catheter (a tube in your bladder)
- blood in the urine.

Do not use EPIRUBE if you are pregnant.

EPIRUBE may harm the unborn child

Do not use EPIRUBE if you are breastfeeding.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you are given it

You must tell your doctor if you:

- have heart problems or have ever had heart problems
- have liver problems
- have kidney problems
- have had radiation therapy previously or are having radiation therapy
- have been treated previously with medicines to treat cancer
- you are going to be vaccinated (have an injection to prevent a certain disease)
- are planning to have children. EPIRUBE may decrease the fertility of men and women.

If you have not told your doctor about any of the above, tell your doctor before you start using EPIRUBE

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your

pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist has more information on medicines to be careful with or avoid while you are receiving EPIRUBE.

Some of these medicines include:

- fluorouracil
- cyclophosphamide
- cisplatin
- paclitaxel
- docetaxel
- trastuzumab
- other medicines to treat cancer
- medicines for the heart
- nifedipine
- verapamil
- diltiazem
- felodipine
- amlodipine
- lercanidipine
- propranolol
- cimetidine
- quinine
- cyclosporine
- vaccines.

You may need to take different amounts of your medicines or you may need to use different medicines. Your doctor will advise you.

Tell your doctor about these things before you are given EPIRUBE.

How it is given

Treatment will normally take place in a hospital. EPIRUBE is usually given as a slow injection or a drip (infusion) into a vein. It might also be injected into the bladder.

Do not drink fluids for 12 hours before treatment if EPIRUBE is to be used in the bladder.

EPIRUBE may be given alone or in combination with other medicines.

Your doctor will decide the dose of EPIRUBE to be given. Treatment is usually given every 3 to 4 weeks, in cycles of therapy. However, your doctor may give EPIRUBE more or less frequently.

Treatment will not be repeated until your blood counts have returned to acceptable levels and any unwanted effects have been controlled.

Your doctor may change your dose during treatment.

Your doctor will let you know how many cycles of treatment you will need.

Ask your doctor if you have any questions about the dose of EPIRUBE and how it is given.

If you take too much (overdose)

As EPIRUBE is likely to be given to you in hospital under the supervision of a doctor, it is unlikely that you will receive too much.

However, immediately tell your doctor or telephone the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital if you have side effects after being given EPIRUBE.

You may need urgent medical attention.

Symptoms of overdose with EPIRUBE include the side effects below in the 'Side Effects' section, but they are usually of a more severe nature.

While you are using it

Things you must do

Tell your doctor or nurse immediately if the injection stings or hurts while it is being given.

The injection may need to be stopped and injected into a different vein.

Make sure you follow your doctor's instructions and keep all appointments.

Your doctor will regularly check the function of your heart, liver and kidneys. You will also need to have blood tests.

Use contraception to prevent pregnancy while you or your partner are being treated with EPIRUBE.

EPIRUBE may cause birth defects if either the male or female is being treated with EPIRUBE. Both men and women being treated with EPIRUBE and their partners must use a reliable method of contraception (birth control) during treatment with EPIRUBE.

Tell your doctor immediately if you become pregnant while using EPIRUBE.

Tell your doctor if you have an infection or fever.

EPIRUBE lowers your ability to fight infection.

Tell your doctor if you would like to take medicine to prevent or treat nausea (feeling sick) or vomiting.

EPIRUBE may cause nausea and vomiting.

Tell any doctor, dentist or pharmacist who treats you that you are being treated with EPIRUBE.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being treated with EPIRUBE.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert, until you know how EPIRUBE affects you.

EPIRUBE may make some people feel tired or dizzy.

Side effects

Tell your doctor as soon as possible if you do not feel well

while you are being treated with EPIRUBE.

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Medicines can affect people in different ways.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor 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)
- 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
- infection
- 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
- gout
- red coloured urine. EPIRUBE is red and may cause the urine to be a red colour for one or days after treatment. There is no cause for alarm.

Tell your doctor immediately if you get any of the following side effects:

- 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.

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above, such as leukaemia, may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

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 EPIRUBE:

- 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 EPIRUBE and other medicines to treat cancer. It is rare.

Storage

This medicine will be stored in the hospital pharmacy and will be looked after by your doctor or pharmacist.

EPIRUBE Injection should be kept in a refrigerator (2-8°C) but do not freeze. Store in the original container.

Product Description

What it looks like

EPIRUBE is a clear red concentrated solution available in vials in packs of 1's.

Strengths include: 10 mg/5 mL, 20 mg/10 mL, 50 mg/25 mL, 150 mg/75 mL and 200 mg/100 mL.

Ingredients

Active ingredient:

The active ingredient in EPIRUBE injection is epirubicin hydrochloride.

Inactive ingredients:

- sodium chloride
- water for injections
- hydrochloric acid may be added for pH adjustment.

Sponsor

Teva Pharma Australia Pty Ltd
37 Epping Rd
Macquarie Park
NSW 2113
Telephone: 1800 28 8382

Australian Registration Numbers:

EPIRUBE 10 mg/5 mL – AUST R 152610

EPIRUBE 200 mg/100 mL – AUST R 152611

EPIRUBE 20 mg/10 mL – AUST R 152612

EPIRUBE 50 mg/25 mL – AUST R 152613

EPIRUBE 150 mg/75 mL – AUST R 152614

This leaflet was revised in June 2016.