

DBL™ Epirubicin Hydrochloride Injection

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

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Epirubicin Hydrochloride Injection (epirubicin hydrochloride).

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given epirubicin against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What DBL™ Epirubicin Hydrochloride Injection 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
- sarcoma
- 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 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 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.

Before you are given DBL™ Epirubicin Hydrochloride Injection

When you must not be given it

You must not be given DBL™ Epirubicin Hydrochloride Injection 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 is not recommended for use during pregnancy. If there is any need to consider epirubicin during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

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

Epirubicin may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are being treated with epirubicin and for at least 12 weeks after you stop treatment. A barrier method of birth control, such as a condom, should be used while you are being given epirubicin and for 12 weeks after the end of treatment. Your doctor will discuss this with you.

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

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

You must not be given this medicine if you have, or have had, any of the following medical conditions:

- heart problems, including a heart attack
- severe or significant liver problems
- a persistently low number of blood cells or platelets due to previous chemotherapy or radiotherapy
- a very inflamed and sore mouth due to previous chemotherapy or radiotherapy

You must not be given this medicine as an infusion into the bladder if you have:

- a tumour that has penetrated the bladder wall
- a urinary infection
- inflammation of the bladder
- insertion of catheter problems
- 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 or another anthracycline medicine.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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

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:

- kidney problems
- mild 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.

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

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 may interfere with each other. These include:

- other medicines used to treat cancer, radiation therapy, or any other treatment which lowers your immune system
- some heart medication, such as propranolol or calcium channel blockers
- cimetidine, medicine used to treat reflux and ulcers
- other medicines that may affect how well your liver works
- some vaccines (ask your doctor).

These medicines may be affected by epirubicin, 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.

How DBL™ Epirubicin Hydrochloride Injection is given

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.

DBL™ Epirubicin Hydrochloride Injection may be given alone or in combination with other drugs.

Several courses of epirubicin 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 you receive.

How it is given

DBL™ Epirubicin Hydrochloride Injection 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 for

Epirubicin 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 DBL™ Epirubicin Hydrochloride Injection 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, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

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

While you are being treated with DBL™ Epirubicin Hydrochloride Injection

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.

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.

Your doctor will monitor your heart regularly before, during and after you are given this medicine.

Epirubicin can affect your heart, particularly after being given high doses or for a long period of time.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of epirubicin 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.

Tell your doctor if you have any infection or fever before, during or after you are given epirubicin.

This medicine will lower your ability to fight infections.

Epirubicin 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 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 driving or operating machinery until you know how epirubicin 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.

Epirubicin can increase your sensitivity to the sun.

Side effects

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

Like other medicines that treat cancer, epirubicin 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 and vomiting
- diarrhoea
- mouth ulcers
- loss of appetite
- fever and chills
- weakness, dizziness, confusion
- hair loss (alopecia)
- increased sensitivity to the sun
- skin rash, itching
- no menstrual periods
- urine discolouration (do not be alarmed if epirubicin 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:

- inflammation or burning in the nose, throat, vagina or rectum
- facial flushing
- any pain, tingling, redness or burning at the site of injection, both during the injection and for the following 24 hours
- painful joints
- painful urination or difficulty urinating, lower back or side pain.

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

After using Epirubicin Hydrochloride Injection

Storage

DBL™ Epirubicin Hydrochloride Injection will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator where the temperature stays between 2-8°C and is protected from light.

Product description

What it looks like

DBL™ Epirubicin Hydrochloride Injection is a clear red solution. It is supplied in glass vials.

Ingredients

Active ingredient:

- Epirubicin hydrochloride

Other ingredients:

- Sodium Chloride
- Water for Injections

DBL™ Epirubicin Hydrochloride Injection does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

DBL™ Epirubicin Hydrochloride Injection is available in the following strengths:

- 50mg/25mL AUST R 83023
- 100mg/50mL AUST R 101582

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