

Epiccord

Epirubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Epiccord.

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 using Epiccord against the benefits it is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What Epiccord is used for

Epiccord 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 Epiccord has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Epiccord is only available with a doctor's prescription. It is not addictive.

Before you are given Epiccord

When you must not be given it

Do not use Epiccord if you have ever had an allergic reaction to epirubicin (the active ingredient

in Epiccord), 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
- problems with a catheter (a tube in your bladder)
- blood in the urine

Do not use Epiccord if you are pregnant.

Epiccord may harm the unborn child.

Do not use Epiccord if you are breastfeeding.

You should not breastfeed while taking Epiccord.

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
Epiccord 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 Epiccord.

Taking other medicines

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

Some medicines and Epiccord may interfere with each other. Some of these medicines include:

- 5-fluorouracil
- cyclophosphamide
- cisplatin
- paclitaxel
- docetaxel
- trastuzumab
- other medicines to treat cancer
- nifedipine
- verapamil
- diltiazem
- felodipine
- amlodipine
- lercanidipine
- propranolol
- cimetidine

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

How Epiccord is given

Treatment will normally take place in a hospital. Epiccord 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 Epiccord is to be used in the bladder.

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

Your doctor will decide the dose of Epiccord to be given.

Treatment is usually given every 3 to 4 weeks, in cycles of therapy. However, your doctor may give Epiccord 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 Epiccord and how it is given.

If you take too much (overdose)

As Epiccord 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

for advice, or go to Accident and Emergency at your nearest hospital if you have side effects after being given Epiccord.

You may need urgent medical attention.

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

While you are using Epiccord

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 Epiccord.

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

Tell your doctor immediately if you become pregnant while taking Epiccord.

Tell your doctor if you have an infection or fever.

Epiccord 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.

Epiccord may cause nausea and vomiting.

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

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

Things to be careful of

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

EPICCORD 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 Epiccord.

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
- 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 colored urine

Epiccord 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 heart beat, 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 Epiccord

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 Epiccord:

- heart problems, fast or irregular heart beat, 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 Epiccord and other medicines to treat cancer. It is rare.

After taking Epiccord

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

Vials of Epiccord Injection should be kept in a refrigerator (2°C to 8°C). Do not freeze.

EPICCORD solution should not be used after 24 hours following the removal from the refrigerator.

Shelf life of the product as package for sale:
2 years

Shelf life after first opening the container:

The vials are for single use only and any unused portion must be discarded after use. From a microbiological point of view, the product should be used immediately after the first penetration of the rubber stopper. If not used immediately, in use storage times and conditions are the responsibility of the user.

Shelf life after dilution of the solution for injection:

Epirubicin Hydrochloride 2 mg/ml Injection may be further diluted, under aseptic conditions, in Glucose 5% or Sodium Chloride 0.9% and administered as an intravenous infusion. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be longer than 24 hours at 2-8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

All material used for preparation, administration or otherwise coming into contact with Epirubicin should undergo disposal according to local guidelines for the handling of cytotoxic compounds.

Product description

What it looks like

Epiccord is a red solution in a vial.

It is available as a liquid injection in 4 sizes: 10 mg/5 mL, 20 mg/10 mL, 50 mg/25 mL and 200 mg/100 mL.

Ingredients

The active ingredient in Epiccord Injection is Epirubicin hydrochloride. It also contains sodium chloride, Hydrochloric acid and water for injections.

Supplier

It is supplied in New Zealand by:

Arrow Pharmaceuticals (NZ) Ltd.
PO Box 128244.
Remuera, Auckland
Telephone : +64 (09) 630-4488

Date of Preparation

October 20, 2010