

EPIRUBICIN ACCORD

Epirubicin Hydrochloride Concentrated Injection
10 mg/5 mL, 20 mg/10 mL, 50 mg/ 25 mL and 200 mg/100 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Epirubicin Accord.

It does not contain all of 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 Epirubicin Accord against the benefits it is expected to have for you.

If you have any concerns about using Epirubicin Accord, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Epirubicin Accord 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 Accord is an anthracycline-type of chemotherapy.

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 Accord 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 Epirubicin Accord

When you must not be given it

Do not use Epirubicin Accord if you have ever had an allergic reaction to epirubicin (the active ingredient in Epirubicin Accord), 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 Epirubicin Accord if you are pregnant.

Epirubicin Accord may harm the unborn child.

Do not use Epirubicin Accord if you are breastfeeding.

You should not breastfeed while taking Epirubicin Accord.

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
Epirubicin Accord 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 Epirubicin Accord.

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 Epirubicin Accord may interfere with each other. Some of these medicines include:

- 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 Epirubicin Accord is given

How much is given

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

Epirubicin Accord may be given alone or in combination with other medicines.

Your doctor will decide the dose of Epirubicin Accord to be given. Treatment is usually given every 3 to 4 weeks, in cycles of therapy. However, your doctor may give Epirubicin Accord 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 Epirubicin Accord and how it is given.

If you take too much (Overdose)

As epirubicin 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 phone the Poisons Information Centre on 13 11 26 or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

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

While you are being given Epirubicin Accord

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 Epirubicin Accord.

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

Tell your doctor immediately if you become pregnant while taking Epirubicin Accord

Tell your doctor if you have an infection or fever.

Epirubicin Accord 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.

Epirubicin Accord may cause nausea and vomiting.

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

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

Things to be careful of

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

Epirubicin Accord may make some people feel tired or dizzy.

Side Effects

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

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), pain on swallowing or difficulty with 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
- gout
- red coloured urine

Epirubicin Accord is red and may cause the urine to be a red colour for one or two 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
- cough, difficulty breathing, chest pain, coughing up blood
- swelling, pain, tenderness and redness of the leg

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 Epirubicin Accord 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 Accord:

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

Storage

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

Product Description

What it looks like

Epirubicin Accord is a clear red solution in a glass vial. It is supplied in vials as single packs. It comes in four sizes (5mL, 10mL, 25mL and 100mL)

Ingredients

Active ingredient:

epirubicin hydrochloride

Inactive ingredients:

sodium chloride

water for injections

hydrochloric acid

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

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

Australian Registration Numbers

10 mg/5 mL: AUST R 210084

20 mg/10 mL: AUST R 210085

50 mg/25 mL: AUST R 210086

200 mg/100 mL: AUST R 227997

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