

# EPIRUBICIN ACCORD

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given Epirubicin Accord?

Epirubicin Accord contains the active ingredient epirubicin hydrochloride. Epirubicin Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. Epirubicin Accord is used to treat various types of cancer. It may be used alone or in combination with other medicines.

For more information, see Section [1. Why am I using Epirubicin Accord?](#) in the full CMI.

### 2. What should I know before I am given Epirubicin Accord?

Do not use if you have ever had an allergic reaction to any medicine containing Epirubicin, other anthracyclines or anthracenediones or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Epirubicin Accord?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Epirubicin Accord and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given Epirubicin Accord?

Epirubicin Accord will be given to you by a doctor or a nurse as a slow injection or a drip (infusion) into a vein. It might also be injected into the bladder.

More instructions can be found in Section [4. How will I be given Epirubicin Accord?](#) in the full CMI.

### 5. What should I know while being given Epirubicin Accord?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Do not drink fluids for 12 hours before treatment if Pharmorubicin RD is to be used in the bladder.</li><li>• Tell your doctor or nurse immediately if the injection stings or hurts while it is being given.</li><li>• Be sure to keep all your doctor's appointments.</li><li>• Use contraception to prevent pregnancy while you or your partner are being treated with Epirubicin Accord. If you become pregnant while you are being given Epirubicin Accord, tell your doctor immediately.</li><li>• Tell your doctor if you have an infection or fever.</li><li>• Tell your doctor if you experience any signs of infection, such as sinusitis, tooth abscess, sore red mouth, fever, sore throat, unusual bleeding or bruising, swollen joints, nausea, vomiting, especially if it lasts for 24 to 48 hours.</li></ul>
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how Epirubicin Accord affects you. Epirubicin Accord may make some people feel tired or dizzy.

For more information, see Section [5. What should I know while being given Epirubicin Accord?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the serious side effects are: 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; 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.

Tell your doctor immediately even if they occur even if this is several months or years after stopping treatment with Epirubicin Accord.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# EPIRUBICIN ACCORD

**Active ingredient(s):** *Epirubicin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Epirubicin Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Epirubicin Accord.**

**Where to find information in this leaflet:**

- [1. Why am I being given Epirubicin Accord?](#)
- [2. What should I know before I am given Epirubicin Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Epirubicin Accord?](#)
- [5. What should I know while being given Epirubicin Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given Epirubicin Accord?

Epirubicin Accord contains the active ingredient Epirubicin hydrochloride. Epirubicin Accord belongs to a group of anticancer medicines known as cytotoxic anthracycline antibiotics. You may also hear of these being called chemotherapy medicines. Epirubicin Accord is an anthracycline-type of chemotherapy. Epirubicin Accord works by killing cancer cells and stopping cancer cells from growing and multiplying.

Epirubicin Accord is used to treat various types of cancer. It may be used alone or in combination with other medicines.

Your doctor, however, may prescribe Epirubicin Accord for another purpose.

## 2. What should I know before I am given Epirubicin Accord?

### Warnings

**You must not be given Epirubicin Accord if:**

- you have an allergy to Epirubicin, other anthracyclines or anthracenediones or any of the ingredients listed at the end of this leaflet.

**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

**You must tell your doctor if you have or have had:**

- heart problems
- liver problems
- kidney problems
- had radiation therapy previously or are having radiation therapy
- been treated previously with medicines to treat cancer

Tell your doctor if you are going to be vaccinated (have an injection to prevent a certain disease)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not use Epirubicin Accord if you are pregnant.**

Epirubicin Accord may harm the unborn child.

Tell your doctor if you are planning to have children. Epirubicin Accord may decrease the fertility of men and women.

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

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

**Do not use Epirubicin Accord if you are breastfeeding.**

You should not breastfeed while taking Epirubicin Accord.

## 3. What if I am taking other medicines?

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

Some medicines and Epirubicin Accord may interfere with each other. These include:

Medicines used to treat cancer, such as:

- 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

A medicine used to treat heartburn or stomach ulcers:

- cimetidine

These medicines and treatments may be affected by Epirubicin Accord or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Epirubicin Accord.**

#### 4. How will I be given Epirubicin Accord?

##### How much will be given

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.

##### When will Epirubicin Accord be given

Epirubicin Accord 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 decide how many of these cycles you will need.

##### If you receive too much Epirubicin Accord

Since Epirubicin Accord is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Epirubicin Accord.

You should immediately:

- contact your doctor or nurse
- phone the Poisons Information Centre (**by calling 13 11 26**)

#### 5. What should I know while 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.

Be sure to keep all your doctor's appointments. Your doctor will regularly check the function of your heart, liver and kidneys. You will also need to have blood tests.

Use contraception (birth control) to prevent pregnancy while you or your partner are being treated with Epirubicin Accord.

If you become pregnant while you are being given Epirubicin Accord, tell your doctor immediately.

Tell your doctor if you have an infection or fever. Epirubicin Accord lowers your ability to fight infection.

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

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

Tell your doctor if you are having or have had radiotherapy.

Tell your doctor if you are having or have had treatment with other anticancer medicines.

Tell your doctor if you have liver problems or kidney problems.

Tell any other doctors, dentists, and pharmacists who treat you. Tell your doctor if you have or have had heart disease or have high blood pressure.

you that you are being given Epirubicin Accord.

##### Driving or using machines

Be careful driving or operating machinery or doing jobs that require you to be alert until you know how Epirubicin Accord affects you. Epirubicin Accord may make some people feel tired or dizzy.

##### Looking after your medicine

The hospital will store Epirubicin Accord under the correct conditions.

##### Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Epirubicin Accord that may be left over.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>nausea (feeling sick) or vomiting</li> <li>diarrhoea</li> <li>sore mouth or tongue, mouth ulcers, redness of mouth, sore vagina or rectum</li> <li>redness of the skin or vein at the site of the injection</li> <li>hair loss, beard stops growing</li> <li>dehydration (thirsty, dry mouth, dry skin, loss of body fluid)</li> <li>sore oesophagus (food pipe), pain on swallowing or difficulty with swallowing</li> <li>stomach pain or burning feeling in stomach</li> <li>skin rash, itchy skin, hives, sensitive skin, blisters</li> <li>change in colour of skin or nails</li> <li>increased sensitivity to the sun</li> <li>itchy eye, crusty eyelid, sore red eye, blurred vision, conjunctivitis</li> <li>loss of appetite</li> <li>absence of menstrual bleeding (temporary loss of periods)</li> <li>hot flushes</li> <li>weakness, tiredness, dizziness, confusion, depression</li> <li>tingling or numbness of hands or feet; pins and needles</li> <li>gout</li> <li>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.)</li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>stinging, swelling or pain at the site of injection</li> <li>flushing of face while the injection is being given</li> <li>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</li> <li>an infection or chills, fever, sore throat, swollen glands, shock</li> <li>heart problems, fast or irregular heartbeat, shortness of breath</li> <li>swelling of ankles, feet, legs or hands</li> <li>bleeding or bruising under the skin</li> <li>cough, difficulty breathing, chest pain, coughing up blood</li> <li>swelling, pain, tenderness and redness of the leg</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

**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.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

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

It is not addictive.

## What Epirubicin Accord contains

<b>Active ingredient (main ingredient)</b>	epirubicin hydrochloride
<b>Other ingredients (inactive ingredients)</b>	sodium chloride hydrochloric acid water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Epirubicin Accord looks like

Epirubicin Accord is a clear red solution in a glass vial. It is supplied in vials as single packs.

(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)

## Who distributes Epirubicin Accord

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

[www.accord-healthcare.com.au](http://www.accord-healthcare.com.au)

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