

PHARMORUBICIN®

Epirubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Pharmorubicin.

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 Pharmorubicin 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 Pharmorubicin is used for

Pharmorubicin 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 Pharmorubicin has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

Before you are given Pharmorubicin

When you must not be given it

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

Pharmorubicin may harm the unborn child.

Do not use Pharmorubicin if you are breastfeeding.

You should not breastfeed while taking Pharmorubicin.

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
Pharmorubicin 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 Pharmorubicin.

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 Pharmorubicin 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 Pharmorubicin is given

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

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

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

Treatment is usually given every 3 to 4 weeks, in cycles of therapy.

However, your doctor may give Pharmorubicin 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 Pharmorubicin and how it is given.

If you are given too much (overdose)

As Pharmorubicin 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 (Phone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you have side effects after being given Pharmorubicin.

You may need urgent medical attention.

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

While you are using Pharmorubicin

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 Pharmorubicin.

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

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

Tell your doctor if you have an infection or fever.

Pharmorubicin 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.

Pharmorubicin may cause nausea and vomiting.

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

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

Things to be careful of

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

PHARMORUBICIN 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 Pharmorubicin.

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
Pharmorubicin 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 Pharmorubicin

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 Pharmorubicin:

- 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 Pharmorubicin 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.

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

Vials of Pharmorubicin RD Powder for Injection should be stored below 25°C.

Product description

What it looks like

Pharmorubicin is a red solution or powder in a vial. There is one vial in each pack.

It is available as a liquid injection and as a powder that is dissolved in a solution before injection.

The powder is not supplied in New Zealand.

Ingredients

The active ingredient in Pharmorubicin Injection is epirubicin hydrochloride. It also contains sodium chloride and water for injections.

The active ingredient in Pharmorubicin RD Powder for Injection is epirubicin hydrochloride. It also contains lactose and methyl hydroxybenzoate.

Supplier

Pharmorubicin is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Toll Free Number: 1800-675 229

It is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland

Toll Free Number: 0800-736 363

*Australian Registration
Numbers*

Pharmorubicin Injection:

- 10 mg/5 mL: AUST R 40098
(not currently supplied)
- 20 mg/10 mL: AUST R 47355
(not currently supplied)
- 50 mg/25 mL: AUST R 47356
- 200 mg/100 mL: AUST R 49746

**Pharmorubicin RD Powder for
Injection 50 mg:**

- AUST R 40220

Date of preparation

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