

# PHARMORUBICIN RD®

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## 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.

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### 1. Why am I being given Pharmorubicin RD?

Pharmorubicin RD contains the active ingredient epirubicin hydrochloride. Pharmorubicin RD is used to treat different types of cancers. It may be used alone or with other medicines.

For more information, see Section [1. Why am I being given Pharmorubicin RD?](#) in the full CMI.

### 2. What should I know before I am given Pharmorubicin RD?

You should not be given this medicine if you have ever had an allergic reaction to Pharmorubicin RD, other medicines to treat cancer 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 Pharmorubicin RD?](#) in the full CMI.

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

Some medicines may interfere with Pharmorubicin RD 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 is Pharmorubicin RD given?**

Pharmorubicin RD is usually given as a slow injection or a drip (infusion) into a vein. It might also be injected into the bladder. It must only be given by a doctor or nurse. Your doctor will decide what dose, how often and how long you will receive it. More instructions can be found in Section [4. How is Pharmorubicin RD given?](#) in the full CMI.

### **5. What should I know while being given Pharmorubicin RD?**

|                             |   |
|-----------------------------|---|
| <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></ul> |
|-----------------------------|---|

- Tell your doctor or nurse immediately if the injection stings or hurts while it is being given.
- Remind any doctor or dentist you visit that you are being given Pharmorubicin RD powder for injection.
- Tell your doctor immediately if you become pregnant while being treated with Pharmorubicin RD. If you have the potential to fall pregnant, you must use effective contraception during treatment. If you are male and your partner has the potential to fall pregnant, you must use effective contraception during your treatment.
- 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.  |
| <b>Driving or using machines</b> | <ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Pharmorubicin RD affects you. It may make some people feel tired or dizzy.</li> </ul> |

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

## 6. Are there any side effects?

Common side effects of this medicine may include: 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 and gout.

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.

# PHARMORUBICIN RD

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pharmorubicin RD. **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 Pharmorubicin RD.**

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

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

## **1. Why am I being given Pharmorubicin RD?**

Pharmorubicin RD contains the active ingredient epirubicin hydrochloride and belongs to a group of anticancer medicines known as cytotoxic anthracycline antibiotics.

Epirubicin hydrochloride works by stopping cancer cells from growing and multiplying. It is used to treat many types of cancers.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

## **2. What should I know before I am given Pharmorubicin RD?**

### **Warnings**

**You should not be given Pharmorubicin RD if:**

- you are allergic to medicines from the same group (anthracyclines or anthracenediones)
- you have an allergy to epirubicin or any of the ingredients listed at the end of this leaflet
- you have a low blood count following chemotherapy or radiotherapy
- you have sore, red mouth from previous treatment or radiation therapy
- you have an infection

- you have severe liver problems
- you have heart disease or heart problems, have recently had a heart attack or experienced chest pain or have a severe form of irregular heartbeats (arrhythmia)
- if you have previously received the total permissible dose of epirubicin or another medicine from the anthracycline group.

### **You should not be given Pharmorubicin RD 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.

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**

You should not be given this medicine if you or your partner are pregnant or planning to become pregnant.

You should not be given this medicine if you are breastfeeding or plan to breastfeed. It is not known whether epirubicin passes into breast milk. Therefore, breastfeeding is not recommended during treatment with epirubicin.



## Contraception

**Use contraception (birth control) to prevent pregnancy while you or your partner are being treated with Pharmorubicin RD.**

Women of childbearing potential should use effective contraception during treatment with epirubicin and for at least 28 weeks after the final dose. Male patients being treated with epirubicin must use effective contraception during treatment and for at least 14 weeks after the final dose if your partner is of childbearing potential. You should seek advice on fertility preservation before treatment.

### **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 may interfere with each other.** These include:

- medicines used to treat cancer such as:
  - 5-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
  - propranolol.
- cimetidine (a medicine used to treat heartburn or stomach ulcers).

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

## **4. How is Pharmorubicin RD given?**

### **How much and how long is it given**

Pharmorubicin RD is given in a clinical setting (e.g. hospital) by a nurse or doctor.

**Do not drink fluids for 12 hours before treatment if Pharmorubicin RD is to be used in the bladder.**

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

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight and height, age,

blood tests, how well your liver is working and whether or not other medicines are being given at the same time.

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

### **If too much Pharmorubicin RD is given**

Since Pharmorubicin RD is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

**However, immediately tell your doctor or telephone the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital if you have side effects after being given Pharmorubicin RD.**

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in [Section 6 Are there any side effects?](#) but are usually of a more severe nature.

## **5. What should I know while being given Pharmorubicin RD?**

### **Things you should 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 (birth control) to prevent pregnancy while you or your partner are being treated with Pharmorubicin RD.**

Tell your doctor immediately if you become pregnant while being treated with Pharmorubicin RD.

**Tell your doctor if you have an infection or fever.**

Pharmorubicin RD lowers your ability to fight infection.

**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.**

You should not be given this medicine if you have severe liver or kidney problems. Your doctor may need to monitor your liver or kidney function and adjust the epirubicin dose if necessary.

**Tell your doctor if you have or have had heart disease or have high blood pressure.**

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

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

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Pharmorubicin RD affects you.**

Pharmorubicin RD may make some people feel tired or dizzy.

## **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.

| <b>Side effects</b>  | <b>What to do</b>  |
|--|--|
| <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></ul> | <p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p> |

| <b>Side effects</b>  | <b>What to do</b>  |
|--|--|
| <ul style="list-style-type: none"> <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.</li> </ul> |  |
| <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>● an infection or chills, fever, sore throat, swollen glands, shock</li> </ul>  | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

| <b>Side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <ul style="list-style-type: none"> <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> |                   |

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

Leukaemia may occur after treatment with Pharmorubicin RD and other medicines to treat cancer. It is rare.

Do not be alarmed by this list of possible side effects.

## **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.

### **What Pharmorubicin RD contains**

|   |                                   |
|---|-----------------------------------|
| <b>Active ingredient<br/>(main ingredient)</b>      | Epirubicin hydrochloride          |
| <b>Other ingredients<br/>(inactive ingredients)</b> | lactose<br>methyl hydroxybenzoate |

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

### **What Pharmorubicin RD looks like**

Pharmorubicin RD is a red-orange powder in a clear glass vial

Australian Registration Numbers

50 mg per vial - AUST R 40220

### **Who distributes Pharmorubicin RD**

Pfizer Australia Pty Ltd

SYDNEY, NSW.

Toll Free Number: 1800 675 229.

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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