

# PHARMACOR DEFERASIROX FC

## 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 using PHARMACOR DEFERASIROX FC?

PHARMACOR DEFERASIROX film-coated tablets contains the active ingredient Deferasirox. PHARMACOR DEFERASIROX FC is used to treat a condition called iron overload, which happens when the body has too much iron.

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

### 2. What should I know before I use PHARMACOR DEFERASIROX FC?

Do not use if you have ever had an allergic reaction to PHARMACOR DEFERASIROX FC 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 use PHARMACOR DEFERASIROX FC?](#) in the full CMI.

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

Some medicines may interfere with PHARMACOR DEFERASIROX FC 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 do I use PHARMACOR DEFERASIROX FC?

- The dose of PHARMACOR DEFERASIROX FC is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.
- Take PHARMACOR DEFERASIROX FC once a day, every day, at about the same time each day with some water.

More instructions can be found in Section [4. How do I use PHARMACOR DEFERASIROX FC?](#) in the full CMI.

### 5. What should I know while using PHARMACOR DEFERASIROX FC?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using PHARMACOR DEFERASIROX FC.</li><li>• Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do regular tests (blood, urine or Magnetic Resonance Imaging (MRI)) to make sure the medicine is working and to prevent unwanted side effects. Your doctor will also use these tests to decide when you should stop taking PHARMACOR DEFERASIROX FC.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their condition seems similar to yours.</li><li>• Do not use it to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how PHARMACOR DEFERASIROX FC affects you.</li><li>• If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in the original container until it is time to take it.</li><li>• Store it in a cool, dry place, below 30°C.</li></ul>

For more information, see Section [5. What should I know while using PHARMACOR DEFERASIROX FC?](#) in the full CMI.

### 6. Are there any side effects?

- Less serious side effects: nausea, diarrhoea, vomiting, pain in the abdomen, bloating, constipation or indigestion, rash, headache, itching, swelling of arms or legs, change in the colour of the skin, anxiety, trouble sleeping, tiredness etc.
- Serious side effects: allergic reaction, severe skin reaction, kidney problem, liver problems, ulcers, gallstones etc.

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.

# PHARMACOR DEFERASIROX FC

**Active ingredient(s):** DEFERASIROX

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PHARMACOR DEFERASIROX FC. **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 PHARMACOR DEFERASIROX FC.**

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

- [1. Why am I using PHARMACOR DEFERASIROX FC?](#)
- [2. What should I know before I use PHARMACOR DEFERASIROX FC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PHARMACOR DEFERASIROX FC?](#)
- [5. What should I know while using PHARMACOR DEFERASIROX FC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using PHARMACOR DEFERASIROX FC?

**PHARMACOR DEFERASIROX FC film-coated tablets contains the active ingredient PHARMACOR DEFERASIROX FC.**

PHARMACOR DEFERASIROX FC is used to treat a condition called iron overload, which happens when the body has too much iron. This can occur after repeated blood transfusions. The body has no natural way to remove excess iron which comes with blood transfusions.

It is also used to treat patients who have iron overload associated with their thalassemia syndromes, but who are not transfusion dependent. In patients with non-transfusion-dependent thalassemia syndromes, iron overload may develop over time due to increased absorption of dietary iron in response to low blood cell counts. Over time, this excess iron can damage important organs such as the liver and heart.

This medicine contains an active substance called PHARMACOR DEFERASIROX FC. It attaches itself to the iron molecules to remove the excess iron from the body. This will help prevent iron-induced organ damage.

It is to be taken every day. This type of medicine must be taken every day to help remove the excess iron from your body.

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.

This medicine is not addictive. This medicine is available only with a doctor's prescription.

## 2. What should I know before I use PHARMACOR DEFERASIROX FC?

### Warnings

- Do not use PHARMACOR DEFERASIROX FC if you are allergic to it, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the 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.
- If you develop a severe rash, or experience difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction) STOP taking it immediately and tell your doctor straight away.
- Do not take this medicine if you have severe kidney problems.
- Do not take this medicine if you have low level of platelets or white blood cell counts.
- Do not take this medicine if you have an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer.
- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

### Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes.
- Have a low level of platelets or white blood cells in your blood test.
- Have or have had any problems with your kidneys or liver.
- Your doctor may want to take special precautions in this case.
- Take any medicines for any other condition

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

### 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.

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

**Some medicines may interfere with PHARMACOR DEFERASIROX FC and affect how it works.** These include:

- cyclosporin, used in transplantation to prevent organ rejection or to treat rheumatoid arthritis or atopic dermatitis
- midazolam (a medicine used to sedate)
- simvastatin (medicines used to lower cholesterol)
- hormonal contraceptive agents (birth control medicines). Their effectiveness may be reduced while taking PHARMACOR DEFERASIROX FC. Use additional contraception.
- certain painkillers or antiinflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids)
- oral bisphosphonates (medicines used to treat osteoporosis)
- anticoagulant medicines (medicines used to prevent or treat blood clotting)
- antacid preparations containing aluminium, which should not be taken at the same time of day as PHARMACOR DEFERASIROX FC
- a medicine for type 2 diabetes called repaglinide
- certain medicines for epilepsy or sedation (phenytoin, phenobarbitone)
- a medicine for HIV called ritonavir
- a medicine for tuberculosis called rifampicin
- a medicine for cancer called paclitaxel
- a medicine used to remove bile acids called cholestyramine
- theophylline (used to treat respiratory diseases such as asthma).
- busulfan (used as treatment prior to bone marrow transplant)

Other medicines that are processed like theophylline in the body and your doctor should know about include: clozapine, cyclobenzaprine, imipramine, haloperidol, fluvoxamine, mexiletine, naproxen, olanzapine, riluzole, tacrine, tizanidine, zileuton and zolmitriptan. Your doctor may need to test the level of some of these medicines in your blood. Your doctor will take these tests into consideration when deciding on the most suitable dose of

these medicines for you. You may need to take different medicines.

Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/ her before you start taking this medicine.

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

### 4. How do I use PHARMACOR DEFERASIROX FC?

#### How much to take

- The dose of PHARMACOR DEFERASIROX FC is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.
- The usual starting dose is 14 mg per kilogram body weight each day for patients receiving regular blood transfusions.
- For patients NOT receiving regular blood transfusions, the usual starting dose is 7 mg per kilogram body weight.
- A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs.
- Depending on your response, your doctor may increase the dose to a maximum 28 mg per kilogram body weight each day if you receive regular blood transfusions or 14 mg per kilogram body weight if you are NOT receiving regular blood transfusions.
- Follow the instructions provided and use deferasirox until your doctor tells you to stop.

#### When to take PHARMACOR DEFERASIROX FC

Take PHARMACOR DEFERASIROX FC once a day, every day, at about the same time each day with some water. Taking PHARMACOR DEFERASIROX FC at the same time each day will help you remember when to take your tablets.

#### How to take PHARMACOR DEFERASIROX FC

- Take the tablets either on an empty stomach or with a light meal.
- The film-coated tablets should not be taken with a high fat meal.
- If you cannot swallow the tablets whole, you can crush them. Then sprinkle all of it onto soft food like yogurt or apple sauce (apple puree). You should then eat it all immediately. Do not keep any to have later.

#### If you forget to use PHARMACOR DEFERASIROX FC

PHARMACOR DEFERASIROX FC should be used regularly at the same time each day. If it is almost time for your next

dose, skip the dose you missed and take the next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much PHARMACOR DEFERASIROX FC**

If you think that you have used too much PHARMACOR DEFERASIROX FC, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. WHAT SHOULD I KNOW WHILE USING PHARMACOR DEFERASIROX FC?**

### **Things you should do**

Elderly patients should be monitored closely by their doctor. Elderly patients may experience more side effects than younger patients and their doctor may adjust their dose.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do regular tests (blood, urine or Magnetic Resonance Imaging (MRI)) to make sure the medicine is working and to prevent unwanted side effects. Your doctor will also use these tests to decide when you should stop taking PHARMACOR DEFERASIROX FC.

Your eyesight and hearing may be tested during treatment as a precautionary measure.

If you become pregnant while taking this medicine, tell your doctor immediately. It may affect your developing baby. Your doctor will discuss the risks and benefits of continuing treatment in this case.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

### **Call your doctor straight away if you:**

- If you notice substantially reduced urine output. This could be a sign of a problem with your kidneys.

Remind any doctor, dentist or pharmacist you visit that you are using PHARMACOR DEFERASIROX FC.

### **Things you should not do**

- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how PHARMACOR DEFERASIROX FC affects you.**

PHARMACOR DEFERASIROX FC may cause dizziness in some people. If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

### **Looking after your medicine**

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool, dry place, below 30°C
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• nausea, diarrhoea, vomiting, pain in the abdomen, bloating, constipation or indigestion</li> <li>• rash</li> <li>• headache</li> <li>• itching</li> <li>• fever or symptoms of a cold or flu</li> <li>• cough or sore throat</li> <li>• dizziness</li> <li>• swelling of arms or legs</li> <li>• change in the colour of the skin</li> <li>• anxiety</li> <li>• trouble sleeping</li> <li>• tiredness</li> <li>• sore muscles or joints</li> <li>• hair loss</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• <b>Any of the following symptoms which may be signs of an allergic reaction:</b> <ul style="list-style-type: none"> <li>• difficulty in breathing and swallowing</li> <li>• swelling of the face, lips, tongue or throat</li> <li>• severe itching of the skin, with a red rash or raised bumps</li> </ul> </li> <li>• <b>Any of the following:</b> <ul style="list-style-type: none"> <li>• rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (signs of severe skin reaction)</li> <li>• a substantially reduced urine output (sign of kidney problem)</li> <li>• drowsiness, upper right abdominal pain, yellowing of your skin or eyes and dark urine (sign of liver problems)</li> <li>• vomiting with blood and/or black stools</li> <li>• frequent heartburn or abdominal pain (ulcers), particularly after eating or taking the drug</li> <li>• blurred, cloudy or partial loss of vision</li> <li>• hearing disturbances</li> <li>• sudden back pain or pain on the right side of the abdomen (signs of gallstones)</li> <li>• severe upper stomach pain (pancreatitis)</li> <li>• tear in stomach or intestine wall</li> </ul> </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>

that can be painful and cause nausea

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

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effect 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 PHARMACOR DEFERASIROX FC contains

Active ingredient (main ingredient)	Deferasirox
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>• Microcrystalline Cellulose</li> <li>• Colloidal anhydrous silica</li> <li>• Povidone</li> <li>• Crospovidone</li> <li>• Poloxamer</li> <li>• Hydrogenated Castor Oil</li> <li>• Sodium Hydroxide</li> <li>• Sodium Stearyl Fumarate</li> <li>• OPADRY Complete Film Coating System 00F505006 Blue (for the 360 mg strength tablet)</li> <li>• OPADRY Complete Film Coating System 00F505007 Blue (for the 90 mg strength tablet)</li> <li>• OPADRY Complete Film Coating System 00F505008 Blue (for the 180 mg strength tablet)</li> </ul>
Potential allergens	No

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

## **What PHARMACOR DEFERASIROX FC looks like**

**PHARMACOR DEFERASIROX FC 90 mg:** Light blue color, film coated oval shaped biconvex tablets, debossed with 'DFX' on the one side and '90' on other side.

**PHARMACOR DEFERASIROX FC 180 mg:** Blue color, film coated oval shaped biconvex tablets, debossed with 'DFX' on the one side and '180' on other side.

**PHARMACOR DEFERASIROX FC 360 mg:** Dark blue color, film coated, oval shaped, biconvex tablets, debossed with 'DFX' on the one side and '360' on other side.

PHARMACOR DEFERASIROX FC available in a Alu-Alu blister pack of 10, 30, 60 & 90 tablets & HDPE Bottle with polypropylene child-resistant closure of 30's & 90's tablets.

### **Australian Register Number:**

PHARMACOR DEFERASIROX FC 90 mg:

Bottle: AUSTR 330587

Blister: AUSTR 330590

PHARMACOR DEFERASIROX FC 180 mg:

Bottle: AUSTR 330582

Blister: AUSTR 330591

PHARMACOR DEFERASIROX FC 360 mg:

Bottle: AUSTR 330580

Blister: AUSTR 330585

### **Who distributes PHARMACOR DEFERASIROX FC**

Pharmacor Pty Ltd.  
CHATSWOOD, NSW 2067,  
Australia

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