

PHARMACOR DEFERASIROX FC

DEFERASIROX

Consumer Medicine Information

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.

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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.