

Consumer Medicine Information

This leaflet provides important information about using EFERAS. **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 EFERAS.**

Where to find information in this leaflet:

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2. What should I know before I use EFERAS?
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1. Why am I using EFERAS?

EFERAS contains the active ingredient deferasirox.

EFERAS 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.

EFERAS 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 cell counts.

Over time, this excess iron can damage important organs such as the liver and heart.

2. What should I know before I use EFERAS?

Warnings

Do not use EFERAS if:

- you are allergic to deferasirox, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as kidney or liver problems
- have low platelet or white blood cell counts
- have an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer
- 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.

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.

These include:

- ciclosporin, used to prevent organ rejection following transplantation or to treat rheumatoid arthritis or atopic dermatitis
- midazolam, a medicine used for sedation
- simvastatin, a medicine used to treat high cholesterol
- hormonal contraceptive agents (birth control medicines). Their effectiveness may be reduced whilst taking EFERAS and therefore additional contraception should be used whilst taking this medicine
- certain painkillers or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids)
- oral bisphosphonates, medicines used to treat osteoporosis
- anticoagulant medicines, medicines used to prevent or treat blood clots
- antacids that contain aluminum should not be taken at the same time of day as EFERAS
- repaglinide, a medicine used for type 2 diabetes
- medicines for epilepsy or sedation (e.g. phenytoin, phenobarbitone)
- ritonavir, a medicine used to treat HIV
- rifampicin, a medicine used to treat tuberculosis
- paclitaxel, a medicine used in the treatment of cancer
- cholestyramine, a medicine used to remove bile acids
- theophylline, a medicine used to treat respiratory diseases such as asthma
- busulfan, a medicine used in treatment prior to bone marrow transplant

Other medicines that are processed in the body like theophylline your doctor should know about include: clozapine, cyclobenzaprine, imipramine, haloperidol, fluvoxamine, mexiletine, naproxen, olanzapine, riluzole, tacrine, tizanidine, zileuton and zolmitriptan.

Some medicines may interfere with EFERAS and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines.

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