

# EFERAS<sup>®</sup>

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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 using EFERAS?

EFERAS contains the active ingredient deferasirox. EFERAS is used to 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. EFERAS is also used to treat patients who have iron overload associated with their thalassemia syndrome (a blood disorder).

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

### 2. What should I know before I use EFERAS?

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

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

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

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 EFERAS?**

- 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 each day.
- Take your medicine either on an empty stomach or with a light meal. Do not take this medicine with a high fat meal.

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

## 5. What should I know while using EFERAS?

<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 EFERAS.</li><li>● Tell your doctor if you are about to have any blood tests.</li><li>● Tell your doctor if you notice your urine output becomes substantially reduced.</li><li>● If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>● Tell your doctor straight away if you become pregnant while taking this medication</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop using this medicine or lower the dosage without checking with your doctor.</li><li>● Do not take EFERAS to treat any other complaints unless your doctor tells you to.</li></ul>

	<ul style="list-style-type: none"> <li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• EFERAS may cause dizziness in some people. If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.</li> <li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> </ul>

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

## 6. Are there any side effects?

Seek immediate medical attention if you experience any difficulty in breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, drowsiness, upper right abdominal pain, yellowing of the skin or eyes and dark urine.

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.

# EFERAS<sup>®</sup>

**Active ingredient:** *deferasirox*

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## Consumer Medicine Information (CMI)

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:**

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

## 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.**

## 4. How do I use EFERAS?

### How much to take

- The dose of EFERAS is related to your body weight. Your doctor will determine the dose you need to take.
- 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 each day.
- A higher or lower starting dose may be recommended by your doctor based on your individual needs.
- Depending on your response, your doctor may increase the dose to a maximum of 28 mg per kilogram body weight daily if you receive regular blood transfusions or 14 mg per kilogram body weight if you are NOT receiving regular transfusions.
- Follow the instructions provided and use EFERAS until your doctor tells you to stop.

### When to take EFERAS

- EFERAS should be used at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Take your medicine either on an empty stomach or with a light meal.

- Do not take this medicine with a high fat meal. Food can interfere with the absorption of this medicine.
- If you cannot swallow the tablets whole, you can crush them. Then sprinkle all of it onto soft food like yoghurt or apple sauce (apple puree). You should then eat it all immediately. Do not keep any to have later.

## **If you forget to use EFERAS**

EFERAS should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicines as you would normally.

**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.**

- This may increase the chance of you getting an unwanted side effect.

## **If you use too much EFERAS**

If you think that you have used too much EFERAS, 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 EFERAS?**

### **Things you should do**

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

- Are about to be started on any new medicines
- Are going to have surgery. Tell the surgeon or anesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- Notice your urine output becomes substantially reduced. This could be a sign of a problem with your kidneys.
- Become pregnant while taking this medicine.
- Are about to have any blood tests. It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are using EFERAS.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests such as blood, urine or magnetic resonance imaging (MIR) to make sure the medicine is working and to prevent unwanted side effects.

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

## **Things you should not do**

- Do not stop using this medicine or lower the dosage without checking with your doctor.
- Do not take EFERAS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

## **Driving or using machines**

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

EFERAS may cause dizziness in some people. If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous.

## **Looking after your medicine**

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• Nausea, diarrhoea, vomiting, pain in the abdomen, bloating, constipation or indigestion</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>These side effects are</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <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 the arms or legs</li> <li>● Change in the colour of your 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>usually mild and short-lived.</b></p>

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</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> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of the following. These are serious side effects that may require medical attention.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● A substantially reduced urine output (sign of kidney problem)</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> </ul>	
<ul style="list-style-type: none"> <li>● Difficulty in breathing or 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> <li>● Drowsiness, upper right abdominal pain, yellowing of the skin</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>Serious side effects</b>	<b>What to do</b>
or eyes and dark urine (signs of liver problems)	

**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 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 EFERAS contains**

<b>Active ingredient (main ingredient)</b>	90 mg, 180 mg or 360 mg deferasirox
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<p><b>Other ingredients (inactive ingredients)</b></p>	<ul style="list-style-type: none"> <li>● colloidal anhydrous silica</li> <li>● crospovidone</li> <li>● magnesium stearate</li> <li>● microcrystalline cellulose</li> <li>● poloxamer</li> <li>● povidone</li> <li>● Opadry Complete Film Coating System 03F505168 Blue (ARTG PI No: 123028)</li> </ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What EFERAS looks like**

EFERAS tablets are available in three different strengths.

EFERAS 90 mg: blue, film coated capsule shaped biconvex tablet debossed with "M" on one side and "DF" on the other (AUST R 331686)

EFERAS 180 mg: blue, film coated capsule shaped biconvex tablet debossed with "M" on one side and "DF1" on the other (AUST R 331685)

EFERAS 360 mg: blue, film coated capsule shaped biconvex tablet debossed with "M" on one side and "DF2" on the other (AUST R 331687)

The tablets are available in blister packs of 30.

## **Who distributes EFERAS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

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

Phone: 1800 274 276

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