

# DEFERASIROX ARX

## 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 DEFERASIROX ARX?

Deferasirox ARX contains the active ingredient Deferasirox. Deferasirox ARX 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.

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

### 2. What should I know before I use DEFERASIROX ARX?

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

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

Some medicines may interfere with Deferasirox ARX 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 DEFERASIROX ARX?

The dose of DEFERASIROX ARX 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.

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

### 5. What should I know while using DEFERASIROX ARX?

<b>Things you should do</b>	If you notice substantially reduced urine output, tell your doctor straight away. If you become pregnant while taking this medicine, tell your doctor immediately.
<b>Things you should not do</b>	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.
<b>Driving or using machines</b>	Be careful driving, operating machinery or doing jobs that require you to be alert until you know how DEFERASIROX ARX affects you.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Do not drink alcohol while taking Deferasirox ARX.</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 25°C</li><li>Do not store this medicine or any other medicine in the bathroom or near a sink</li><li>Do not leave it in the car or on window sills.</li></ul>

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

### 6. Are there any side effects?

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.

# DEFERASIROX ARX

Active ingredient(s): [DEFERASIROX]

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Deferasirox ARX. **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 Deferasirox ARX.**

Where to find information in this leaflet:

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

## 1. Why am I using DEFERASIROX ARX?

**Deferasirox ARX contains the active ingredient deferasirox.**

Deferasirox ARX 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.

DEFERASIROX ARX 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 deferasirox. It attaches itself to the iron molecules to remove the excess iron from the body. This will help prevent iron-induced organ damage.

**DEFERASIROX ARX 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 DEFERASIROX ARX?

### Warnings

**Do not use Deferasirox ARX if:**

**Do not take DEFERASIROX ARX if you have an allergy to deferasirox, the active ingredient, or to any of the other ingredients listed at the end of this leaflet.**

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 DEFERASIROX ARX 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:**

Tell your doctor if you have a low level of platelets or white blood cells in your blood test.

Tell your doctor if you have or have had any problems with your kidneys or liver.

Your doctor may want to take special precautions in this case.

### **Pregnancy and breastfeeding**

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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.

Some medicines and DEFERASIROX ARX may interfere with each other. These include:

- ciclosporin, 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 DEFERASIROX ARX. Use additional contraception.
- 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 clotting)
- antacid preparations containing aluminium, which should not be taken at the same time of day as DEFERASIROX ARX
- 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 DEFERASIROX ARX.**

### **4. How do I use DEFERASIROX ARX?**

DEFERASIROX ARX is a different formulation of EXJADE® with the same active ingredient, deferasirox; however, the dose will change when switching between EXJADE and DEFERASIROX ARX.

#### **How much to take / use**

The dose of DEFERASIROX ARX 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.

#### **When to take / use Deferasirox ARX**

- Take DEFERASIROX ARX once a day, every day, at about the same time each day with some water.
- 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.

Taking DEFERASIROX ARX at the same time each day will help you remember when to take your tablets.

**Do not stop taking DEFERASIROX ARX unless your doctor tells you to - even if you feel well.**

This medicine helps to control your condition but does not cure it. Therefore, you must take it every day. Continue taking the medicine as long as your doctor tells you to.

#### **If you forget to use Deferasirox ARX**

Deferasirox ARX should be used regularly at the same time each day. If you miss your dose at the usual time, If it is almost time for your next dose, skip the dose you missed and take your 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 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.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

#### **If you use too much Deferasirox ARX**

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DEFERASIROX ARX. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

If you have taken too much DEFERASIROX ARX, You may experience effects such as abdominal pain, nausea, vomiting, headache, diarrhoea and kidney or liver problems that can be serious.

## **5. What should I know while using DEFERASIROX ARX?**

### **Things you should do**

**If you notice substantially reduced urine output, tell your doctor straight away.**

This could be a sign of a problem with your kidneys.

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 DEFERASIROX ARX.

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.

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

### **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 driving, operating machinery or doing jobs that require you to be alert until you know how DEFERASIROX ARX affects you.

This medicine 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 25°C
- Do not store this medicine or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on window sills.

## Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## When to discard your medicine

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.**

## 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.

**Elderly patients may experience more side effects than younger patients.**

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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></ul>	<p><b>Tell your doctor or pharmacist if you notice any of the following and they worry you</b></p> <p>The above list includes the more common side effects of</p>

<ul style="list-style-type: none"><li>• anxiety</li><li>• trouble sleeping</li><li>• tiredness</li><li>• sore muscles or joints</li><li>• hair loss</li></ul> <ul style="list-style-type: none"><li>• signs of severe skin reaction: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes</li><li>• sign of kidney problem: a substantially reduced urine output.</li><li>• sign of liver problems: drowsiness, upper right abdominal pain, yellowing of your skin or eyes and dark urine</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>• signs of gallstones: sudden back pain or pain on the right side of the abdomen</li><li>• pancreatitis: severe upper stomach pain</li><li>• tear in stomach or intestine wall that can be painful and cause nausea</li></ul>	<p>your medicine. They are usually mild and short-lived.</p> <p><b>STOP taking DEFERASIROX ARX and tell your doctor immediately if you notice any of the following:</b></p> <p>The above list includes serious side effects which may require medical attention. These side effects do not occur frequently.</p>
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## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• difficulty in breathing and swallowing.</li><li>• swelling of the face, lips, tongue or throat</li></ul> <p>severe itching of the skin, with a red rash or raised bumps.</p>	<p><b>STOP taking DEFERASIROX ARX and seek medical help immediately if you or your child experience any of the following symptoms which may be signs of an allergic reaction</b></p>

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

Some people may have other side effects not yet known or mentioned in this leaflet. Some of these side effects, for example, changes in kidney and liver function, can only be found when your doctor does tests from time to time to check your progress.

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 Deferasirox ARX contains

<b>Active ingredient (main ingredient)</b>	Contains either 90, 180 or 360 mg of deferasirox as the active ingredient
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• crospovidone</li> <li>• povidone</li> <li>• magnesium stearate</li> <li>• colloidal anhydrous silica</li> <li>• poloxamer</li> <li>• sodium starch glycollate type A</li> <li>• Opadry complete film coating system 00F505018 Blue (PI 119880) (90mg strength)</li> <li>• Opadry complete film coating system 00F505011 Blue (PI 111352) (180mg strength)</li> <li>• Opadry complete film coating system 00F505017 Blue (PI 119879) (360mg strength)</li> </ul>

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

### What Deferasirox ARX looks like

DEFERASIROX ARX 90 mg film-coated tablets: Light blue oval, biconvex, film-coated tablet with bevelled edges, debossed with "L" on one side and "663" on the other side. Approximately 10 mm in length and approximately 4 mm in width.

DEFERASIROX ARX 180 mg film-coated tablets: Medium blue oval, biconvex, film-coated tablet with bevelled edges, debossed with "L" on one side and "664" on the other side. Approximately 13 mm in length and approximately 5 mm in width.

DEFERASIROX ARX 360 mg film-coated tablets: Dark blue oval, biconvex, film-coated tablet with bevelled edges, debossed with "L" on one side and "665" on the other side. Approximately 17 mm in length and approximately 7 mm in width.

DEFERASIROX ARX comes in packs of 30 tablets in a carton containing 3 Al/Al or PVC/PVdC/Al blisters of 10 tablets.

### Who distributes Deferasirox ARX

Arrotex Pharmaceuticals Pty Ltd.

15 – 17 Chapel Street, Cremorne  
VIC 3121

Australian Registration Number.

DEFERASIROX ARX 90 mg  
AUST R 326702

DEFERASIROX ARX 180 mg

AUST R 326675

DEFERASIROX ARX 360 mg

AUST R 326680

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