

Deferasirox Sandoz®

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 Sandoz?

Deferasirox Sandoz contains the active ingredient deferasirox. Deferasirox Sandoz 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 Deferasirox Sandoz?](#) in the full CMI.

2. What should I know before I use Deferasirox Sandoz?

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 Deferasirox Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Deferasirox Sandoz and affect how it works. Check with your doctor or pharmacist if you are not sure what to do.

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 Sandoz?

- Take your medicine either on an empty stomach or with a light meal. Do not take this medicine with a high fat meal.
- Your doctor will tell you how many tablets to take.

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

5. What should I know while using Deferasirox Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Deferasirox Sandoz.• Keep all medical appointments so your progress can be checked.• Tell your doctor if you notice that your urine output has decreased a lot.• Tell your doctor immediately if you become pregnant while taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without checking with your doctor.• Do not give this medicine to anyone else, even if their condition seems similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Deferasirox Sandoz may cause dizziness in some people. Be careful before you drive or use any machines or tools until you know how Deferasirox Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects include feeling sick, vomiting, diarrhoea, pain in tummy, headache, rash. Seek immediate medical attention if you experience 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.

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 Sandoz®

Active ingredient(s): *deferasirox*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Deferasirox Sandoz?

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

It is an iron binding agent which attaches itself to the iron molecules in your body to remove excess iron. The body has no natural way to remove excess iron which comes with blood transfusions. Over time, this excess iron can damage important organs such as the liver and heart.

Deferasirox Sandoz is used to treat a condition called iron overload, which happens when the body has too much iron:

- in patients 6 years and older, due to blood transfusions. This can occur after repeated blood transfusions.
- in patients aged 2 to 5 years who are unable to take desferrioxamine (alternative therapy) or in whom desferrioxamine has proven ineffective.
- in patients 10 years and older with thalassemia syndromes who are not transfusion dependent.

2. What should I know before I use Deferasirox Sandoz?

Warnings

Do not use Deferasirox Sandoz if:

- you are allergic to deferasirox, or any of the 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.

Always check the ingredients to make sure you can use this medicine.

- you have severe kidney problems;
- you have low levels of platelet counts;
- you have an advanced stage of myelodysplastic syndrome (MDS) or other cancers and not expected to benefit from chelation treatment.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives, or dyes;
- take any medicines for any other condition
- have problems with your kidney or liver;
- have abnormal blood tests results such as low level of platelets or white blood cells;
- have a history of stomach ulcers.

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 with the treatment.

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 may interfere with Deferasirox Sandoz and affect how it works. 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 lower cholesterol
- hormonal contraceptive agents (birth control medicines). They may not work as well while taking Deferasirox Sandoz. Use additional contraception while taking Deferasirox Sandoz.
- 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 aluminum, should not be taken at the same time of day as Deferasirox Sandoz
- repaglinide, a medicine for type 2 diabetes
- certain medicines for epilepsy or sedation, e.g. phenytoin, phenobarbitone
- ritonavir, a medicine to treat HIV
- rifampicin, a medicine to treat tuberculosis
- paclitaxel, a medicine used in the treatment of cancer
- colestyramine, a medicine used to remove bile acids
- theophylline, a medicine used to treat respiratory diseases such as asthma
- busulfan, a medicine used as treatment prior to bone marrow transplant.

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 Deferasirox Sandoz.**

4. How do I use Deferasirox Sandoz?

Follow the instructions provided and take Deferasirox Sandoz until your doctor tells you to stop.

How much to take

- The dose of Deferasirox Sandoz 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 to the treatment, your doctor might reduce or increase the dose. Consult your doctor if you do not understand your dose.

When and how to take Deferasirox Sandoz

- Take Deferasirox Sandoz once a day with a glass of water at about the same time each day.
- Take Deferasirox Sandoz on an empty stomach or with a light meal.
- Do not take Deferasirox Sandoz 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 eat it all immediately. Do not keep any to have later

If you forget to use Deferasirox Sandoz

Deferasirox Sandoz 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 take the next dose as usual.

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 Deferasirox Sandoz

If you think that you have used too much Deferasirox Sandoz, 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 Deferasirox Sandoz?

Things you should do

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

- Your doctor will ask you to do regular blood, urine and/or Magnetic Resonance Imaging (MRI) tests 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.

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

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

Call your doctor straight away if you:

- notice a decrease in your urine output. This could be a sign of a kidney problem.
- become pregnant while taking this medicine. Your doctor will discuss the risks and benefits of continuing treatment.
- develop peeling or blistering of the skin and flu-like symptoms.

Things you should not do

- Do not stop using this medicine suddenly or change the dose without checking with your doctor.
- Do not use it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their condition seems similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Deferasirox Sandoz affects you.

Deferasirox Sandoz 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.

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, at room temperature (below 30°C), away from moisture, heat, or sunlight.
- 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 windowsills. Follow the instructions in the carton on how to take care of your medicine properly.
- Follow the instructions in the carton on how to take care of your medicine properly.

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"> • Diarrhoea • Constipation • Feeling sick, vomiting • Pain in your tummy • Indigestion, bloating • Headache • Dizziness • Rash • Itching • Anxiety • Trouble sleeping • Tiredness • Sore muscles or joints • Hair loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <ul style="list-style-type: none"> • Swelling of the face, lips, mouth tongue or throat. 	<p>Call your doctor straight away, or go straight to the</p>

<ul style="list-style-type: none"> • Difficulty in swallowing or breathing. • Severe itching of the skin, with a red rash or raised bumps. <p>Stomach problems:</p> <ul style="list-style-type: none"> • Vomiting with blood and/or black stools. • Frequent heartburn or pain in the tummy particularly after eating or taking the medicine • Severe abdominal pain or cramping, fever or chills, feeling sick, vomiting • Severe pain in the upper belly • Sudden back pain or pain on the right side of the belly <p>Eye & Ear problems:</p> <ul style="list-style-type: none"> • Blurred, cloudy or partial loss of vision • Trouble hearing <p>General</p> <ul style="list-style-type: none"> • Rash, red skin, blistering of the lips, eyes or mouth, skin peeling • high fever, flu-like symptoms • A large decrease in urine output • Drowsiness, pain in the upper right side of your tummy, yellowing of your skin or eyes and dark urine 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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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.

Some side effects can only be found when your doctor does tests from time to time to check your progress, for example, changes in kidney and liver function.

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. 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 Sandoz contains

Active ingredient (main ingredient)	deferasirox
Other ingredients (inactive ingredients)	microcrystalline cellulose crospovidone povidone

	magnesium stearate colloidal anhydrous silica poloxamer hypromellose titanium dioxide macrogol 4000 purified talc indigo carmine aluminium lake
Potential allergens	None

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

What Deferasirox Sandoz looks like

Deferasirox Sandoz is available in three different strengths and is supplied in packs of 30 film -coated tablets in blister packs:

Deferasirox Sandoz 90 mg – Light blue ovaloid film-coated tablet with bevelled edges, debossed with 'NVR' on one side and '90' on a slight upward slope in between two debossed curved lines on the other side. (Aust R 362210).

Deferasirox Sandoz 180 mg - Medium blue ovaloid film-coated tablet with bevelled edges, debossed with 'NVR' on one side and '180' on a slight upward slope in between two debossed curved lines on the other side. (Aust R 362211).

Deferasirox Sandoz 360 mg - Dark blue ovaloid film -coated tablet with bevelled edges, debossed with 'NVR' on one side and '360' on a slight upward slope in between two debossed curved lines on the other side. (Aust R 362235).

Who distributes Deferasirox Sandoz

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