

DEFERASIROX SANDOZ®

deferasirox

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEFERASIROX SANDOZ.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What DEFERASIROX SANDOZ is used for

DEFERASIROX SANDOZ 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 SANDOZ 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 SANDOZ 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.

Before you take DEFERASIROX SANDOZ

When you must not take it

Do not take DEFERASIROX SANDOZ 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 SANDOZ 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DEFERASIROX SANDOZ may interfere with each other. 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 DEFERASIROX SANDOZ. 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 SANDOZ

- 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.

How to take DEFERASIROX SANDOZ

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.

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

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, 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.

How to take it

- Take DEFERASIROX SANDOZ 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 SANDOZ at the same time each day will help you remember when to take your tablets.

How long to take it

Do not stop taking DEFERASIROX SANDOZ 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 take it

If it is almost time for your next dose, skip the dose you missed and take the 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 that 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.

If you take too much (overdose)

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 SANDOZ. 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 SANDOZ, you may experience effects such as abdominal pain, nausea, vomiting,

headache, diarrhoea and kidney or liver problems that can be serious.

While you are taking DEFERASIROX SANDOZ

Things you must 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 SANDOZ.

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.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must 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.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how DEFERASIROX SANDOZ 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DEFERASIROX SANDOZ even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

STOP taking DEFERASIROX SANDOZ and seek medical help immediately if you or your child experience any of the following symptoms which may be signs of an allergic reaction:

- difficulty in breathing and swallowing
- swelling of the face, lips, tongue or throat

- severe itching of the skin, with a red rash or raised bumps

STOP taking DEFERASIROX SANDOZ and tell your doctor immediately if you notice any of the following:

- 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)
- a substantially reduced urine output (sign of kidney problem)
- drowsiness, upper right abdominal pain, yellowing of your skin or eyes and dark urine (sign of liver problems)
- vomiting with blood and/or black stools
- frequent heartburn or abdominal pain (ulcers), particularly after eating or taking the drug
- blurred, cloudy or partial loss of vision
- hearing disturbances
- sudden back pain or pain on the right side of the abdomen (signs of gallstones)
- severe upper stomach pain (pancreatitis)
- tear in stomach or intestine wall that can be painful and cause nausea

The above list includes serious side effects which may require medical attention. These side effects do not occur frequently.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, diarrhoea, vomiting, pain in the abdomen, bloating, constipation or indigestion
- rash
- headache
- itching
- fever or symptoms of a cold or flu
- cough or sore throat
- dizziness
- swelling of arms or legs

- change in the colour of the skin
- anxiety
- trouble sleeping
- tiredness
- sore muscles or joints
- hair loss

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor or pharmacist if you notice anything that is 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.

After using DEFERASIROX SANDOZ

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool, dry place, below 30°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 the medicine where children cannot reach it.

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

Disposal

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.

Product description

What it looks like

DEFERASIROX SANDOZ 90 mg film-coated tablets: 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.

DEFERASIROX SANDOZ 180 mg film-coated tablets: 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.

DEFERASIROX SANDOZ 360 mg film-coated tablets: 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

DEFERASIROX SANDOZ comes in packs of 30 film-coated tablets in blister packs.

Ingredients

Contains either 90, 180 or 360 mg of deferasirox as the active ingredient. It also contains:

- microcrystalline cellulose
- crospovidone
- povidone
- magnesium stearate
- colloidal anhydrous silica
- poloxamer
- hypromellose
- titanium dioxide
- macrogol 4000
- purified talc
- indigo carmine aluminium lake

Sponsor

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060

Australia

Tel 1800 726 369

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DEFERASIROX SANDOZ 90 mg
AUST R 362210

DEFERASIROX SANDOZ 180 mg
AUST R 362211

DEFERASIROX SANDOZ 360 mg
AUST R 362235

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