Novartis
Oncology

My Exjade®▼ (deferasirox) Handbook

Name:

Date:

▼This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly to HPRA Pharmacovigilance at www.hpra.ie. Side effects can also be reported to Novartis preferably at www.novartis.com/report, by emailing drugsafety.dublin@novartis.com or by calling (01) 2080 612.

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Exjade® (deferasirox) Handbook

This handbook contains important information, including how to take Exjade® the right way. You will learn about monitoring your treatment, possible side effects, and taking other medicines while on Exjade®.

Deferasirox is available in a film-coated tablet, and each dose has a different size and colour

It is important to take your medicine as directed by your physician.

- Exjade® film-coated tablets are blue, oval tablets that may be swallowed whole on an empty stomach or with a light meal. If you are unable to swallow whole tablets, Exjade® film-coated tablets may be crushed and sprinkled onto soft food.



Tablets displayed are not actual size.

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What is Exjade® (deferasirox)?

Exjade® is an iron chelator (or chelating agent) that is used to help remove excess iron in the body.

Why was I prescribed Exjade®?

Many kinds of conditions need transfusions. Some of these are:

- β-thalassemia major
- Sickle cell disease, or SCD
- Lower-risk myelodysplastic syndromes, or MDS
- Other anemias

If you have one of these conditions, you've probably been given a few transfusions. Transfusions have the healthy red blood cells your body needs and can help you feel better.

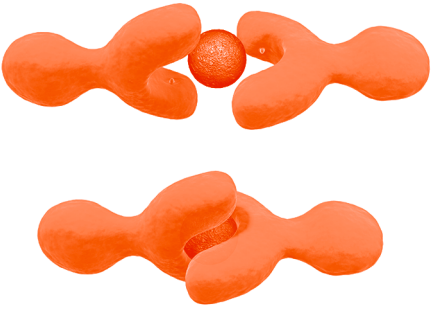
Every transfusion you are given contains iron. Iron is important because red blood cells use it to carry oxygen around your body. However, the body does not have its own way of removing extra iron.

The amount of iron builds up with each transfusion. This causes extra iron in your body, called **chronic iron overload**. Too much iron can be harmful and damage organs like your heart and liver.

It is important to remove this extra iron to keep your iron at a safe, healthy level.

How does Exjade® work?

Exjade® works by a process called "**chelation**" (key-lay-shun). After you have taken Exjade®, it enters your blood and "captures" extra iron it finds.



What is Exjade® used for?

Exjade® is used to treat chronic iron overload caused by frequent blood transfusions in patients with β-thalassemia major aged 6 years and older.

Exjade® is also used to treat chronic iron overload when deferoxamine therapy is contraindicated or inadequate in patients with beta thalassemia major with iron overload caused by infrequent blood transfusions, in patients with other types of anemias, and in children aged 2 to 5 years.

Exjade® is also used when deferoxamine therapy is contraindicated or inadequate to treat patients aged 10 years or older who have iron overload associated with their thalassemia syndromes, but who are not transfusion dependent.

How do I take Exjade® (deferasirox) film-coated tablets?

What dose will I take?

Your prescribed dose of Exjade® film-coated tablets is based on your weight, current iron level, liver and kidney function, and how often you get transfusions.

If you are changing from deferoxamine infusions to Exjade® film-coated tablets, your doctor may choose your Exjade® dose based on how much deferoxamine you have been taking.

In some countries, deferasirox may also be available as dispersible tablets, made by other manufacturers. In case of switch from deferasirox dispersible tablets to Exjade® film-coated tablets, a lower dose than the deferasirox dispersible tablets will have to be taken. Your doctor will calculate the dose you need and tell you how many film-coated tablets to take each day. If you don't take the adjusted lower dose as directed by your physician on your prescription for Exjade® film-coated tablets, you may inadvertently take more Exjade® than you should and then you may experience adverse overdose reactions. In this case, inform your doctor immediately or contact emergency services, as medical treatment may be necessary (see page 9). You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting and kidney or liver problems that can be serious.

Which tablet(s) will I take?

Exjade® film-coated tablets comes in different tablet sizes, and you may need to take more than one. Your doctor will tell you how many tablets and which size(s) you should take each day.



90 mg



180 mg



360 mg

Tablets shown actual size.

When will I take Exjade® film-coated tablets?

Exjade® film-coated tablets should be taken once a day, preferably at the same time each day, and may be taken on an empty stomach or with a light meal.

How to take Exjade® film-coated tablets

Exjade® film-coated tablets should be swallowed whole with some water. For patients who are unable to swallow whole tablets, the Exjade® film-coated tablets may be crushed and administered by sprinkling the full dose onto a small amount of soft food, such as yogurt or applesauce (puréed apple). The dose should be immediately and completely consumed, and not stored for future use.

What if I forget to take my dose?

If you miss taking a dose of Exjade®, you should still take it when you remember, even if it is later in the day. Take your next dose as scheduled.

Do not take a double dose on the next day to make up for the forgotten tablet(s).

What if I take more Exjade® tablets than I should?

If you take more Exjade® tablets than you should, inform your doctor immediately or contact emergency services, as medical treatment may be necessary.

How will my treatment be monitored?

While taking Exjade® (deferasirox), you will have regular laboratory tests. These tests will monitor how you are responding to treatment. Your dose may have to be adjusted up or down based on these tests.

Test	Before starting Exjade®	Every month	Once per year
Iron* Serum ferritin	✓	✓	
Kidneys Serum creatinine (Serum creatinine is measured in duplicate at baseline.)	✓ This blood test will be taken **twice** before starting Exjade®	✓ For the first month and in the first month after any changes in dose, you will be tested once per week; then once per month	
Creatinine clearance	✓	✓ For the first month and in the first month after any changes in dose, you will be tested once per week; then once per month	
Liver (Serum transaminases, bilirubin, alkaline phosphatase)	✓	✓ For the first month, you will be tested every 2 weeks; then once per month	
Urine (Protein in urine)	✓	✓	
Hearing and vision	✓		✓ For paediatric patients
Pediatric patients: Assess body development (eg, your weight, sexual development, and how much you grow per year)	✓		✓
Weight and height	✓		✓

*For non transfusion dependent patients, Liver ion concentration (LIC)should be monitored every 3 months when serum ferritin is ≤800 µg/l

Your doctor may also

- Use a test called magnetic resonance imaging, or MRI, to check iron levels in your heart or liver
- Perform a biopsy of your kidneys if he/she suspects important kidney problems
- Perform monitoring for other Tests including: markers of renal tubular function (such as glycosuria in non-diabetics and low levels of serum potassium, phosphate, magnesium or urate, phosphaturia, aminoaciduria) as needed

Does Exjade® have side effects?

Like all medicines, Exjade® can have side effects, though not all patients experience them. The most frequent side effects are mild to moderate and will generally disappear once you get used to treatment. This can take a few days or weeks.

Common side effects include nausea, vomiting, diarrhoea, pain in the abdomen, bloating, constipation, indigestion, skin rash, headache, and itching.

Your kidney and liver function will be tested before you start Exjade® and you will be monitored regularly during treatment. (See table on previous page.)

Some side effects could be serious and need immediate medical attention.

Remember: Always tell your health care provider about any side effects you experience. If you have any serious side effects, STOP taking your medication and contact your doctor immediately.

For more details on side effects and serious side effects, please see the Patient Leaflet.

What about other medicines that I also need to take for my health?

Exjade® (deferasirox) must not be taken with other chelators.

Antacids (medicines used to treat heartburn) containing aluminum should not be taken at the same time of day as Exjade® (deferasirox).

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicine you take without a prescription. Your doctor may need to do laboratory tests to monitor these medicines.

Important medicines to tell your doctor about include, in particular:

- Other iron chelators, which must not be taken with Exjade®
- Antacids (medicines used to treat heartburn) containing aluminum, which should not be taken at the same time as Exjade®
- Cyclosporine (used to prevent the body from rejecting a transplanted organ or for other conditions, such as rheumatoid arthritis or atopic dermatitis)
- Simvastatin (used to lower cholesterol)
- Certain painkillers or anti-inflammatory medicines (eg, aspirin, ibuprofen, corticosteroids)
- Oral bisphosphonates (used to treat osteoporosis)
- Anticoagulant medicines (used to prevent or treat blood clotting)
- Hormonal contraceptive agents (birth control medicines)*
- Bepridil (a calcium channel blocker)
- Ergotamine (used as a treatment for migraine)
- Repaglinide (used to treat diabetes)
- Rifampicin (used to treat tuberculosis)
- Phenytoin, phenobarbital, carbamazepine (used to treat epilepsy)
- Ritonavir (used in the treatment of HIV infection)
- Paclitaxel (used in cancer treatment)
- Theophylline (used to treat respiratory diseases such as asthma)
- Clozapine (used to treat psychiatric disorders such as schizophrenia)
- Tizanidine (used as a muscle relaxant)
- Cholestyramine (used to lower cholesterol levels in the blood)
- Midazolam (used as a sedative and to treat anxiety and amnesia)

Contraception

If you are currently using an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (eg, condom), as Exjade® may reduce the effectiveness of oral and patch contraceptives.

My progress with Exjade®

My treatment goal

The goal of Exjade® treatment is to have a healthy amount of iron in your body. Each month you will visit your doctor to track your progress toward your **treatment goal**.

Your doctor will set your treatment goals based on a blood test called a serum ferritin (SEER-um FAIR-it-in) test. This test gives your serum ferritin level, or **SF level**. Your SF level tells your doctor how much iron is in your body. Your doctor will want to either lower your SF level or keep it where it is.

My dose

Your doctor may decide to change your dose based on your SF level, other laboratory tests, or how often you get transfusions.

After taking Exjade® for **3 to 6 months**, check with your doctor that you are making progress as planned. If you are not, ask your doctor about his/her plan for helping you reach your treatment goal.

Between each visit

Other important events may occur between doctor visits. You should keep a record of them and share them with your doctor. They include:

- Side effects
- Other medicines
- Any deviation from the prescribed dose

My background information

Your background information is helpful for both you and your doctor when planning your treatment with Exjade® (deferasirox). Ask your doctor if you need help answering these questions.

General information

First name _____

Last name _____

Date of birth _____

Diagnosis _____

Have I been given transfusions? If so, how many and how often?

Do I have any other health issues?

Am I taking any medicine right now for other health issues?

Do I have any allergies?

Starting Exjade®

You can start tracking your progress once your doctor decides on your goal SF level and dose of Exjade®. Work with your doctor to fill in your treatment goals and other information, below.

Date: _____ **My current SF level:** _____

My treatment goal is to:

Reduce my SF level to

_____

My weight:

_____

My Exjade® dosing regimen:

I am taking

☐ Exjade® film-coated tablets

- How many tablets will I take each day?

_____

Exjade® film-coated tablets:

☐ I can swallow my tablets whole

☐ I will crush my tablets and sprinkle them on a soft food such as yogurt or applesauce (puréed apple) and eat it immediately

- When will I take my medication each day?

_____

Notes: Write down any notes or questions from your visit.

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