

My Exjade® (deferasirox) Handbook

NAME _____

DATE _____



This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Suspected adverse reactions and medication errors associated with the use of Exjade should be reported to:

Malta Medicines Authority,
Sir Temi Zammit Buildings,
Malta Life Sciences Park,
San Gwann. SGN 3000.

Or at: www.medicinesauthority.gov.mt/adrportal.

Alternatively at: Novartis Pharma Services Inc., Representative Office, Malta by phone on +356 21222872.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.

Local Representative: Novartis Pharma Services Inc.,
Representative Office Malta.
Tel No.: +356 21222872

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Introduction: Exjade® (deferasirox) Handbook

This handbook contains important information about Exjade. You'll learn about taking Exjade the right way, depending on which form your doctor prescribed, as well as about monitoring your treatment, possible side effects, and taking other medicines while on Exjade.

Exjade dispersible tablets will no longer be available in the European Union in the near future. Your physician may instead prescribe the film-coated tablet version (as per availability in your country) of the same deferasirox medication you have been taking. The film-coated tablet version prescription will be at a lower dose than the dispersible tablets. If you don't take the adjusted lower dose as directed by your physician on your prescription for the 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.

Deferasirox is available in multiple forms. Each has a specific shape and color and is taken differently

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

- 1) Exjade film-coated tablets are blue, oval tablets. They 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.



- 2) Exjade dispersible tablets are white to slightly yellow, round tablets. They must be dissolved in liquid and taken on an empty stomach.



Tablets displayed are not actual size.

What is Exjade® (deferasirox)?

Exjade helps to remove excess iron in the body. Because of this, it is known as an “iron chelator” or “chelation agent.”

Why was I prescribed Exjade?

Many kinds of conditions need blood 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 received several blood 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, and this extra iron in your body, may lead to a condition 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 swallow Exjade, Exjade enters your blood and “captures” extra iron available.



What is Exjade used for?

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

Exjade is also used to treat chronic iron overload when a medication called deferoxamine should not be used or did not improve outcomes in patients with β -thalassemia major and iron overload caused by infrequent blood transfusions, in patients with other types of blood disorders called anemias, and in children aged 2 to 5 years.

Exjade is also used when deferoxamine should not be used or did not improve outcomes in 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 switching from Exjade® (deferasirox) dispersible tablets to Exjade film-coated tablets, you will need a lower dose. If you are changing from a different medication (such as deferoxamine) to Exjade film-coated tablets, your doctor may choose your Exjade dose based on how much of the previous medication you were taking.

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.

Exjade film-coated tablets



Tablets shown actual size.

How and when to take Exjade film-coated tablets

Exjade film-coated tablets should be swallowed whole with some water. If you're unable to swallow whole tablets, you can crush the Exjade film-coated tablets and sprinkle the full dose onto a small amount of soft food, such as yogurt or applesauce (puréed apple).

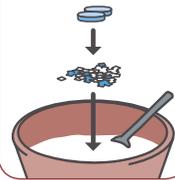
You should immediately and completely consume the entire dose and not store any for future use.

Exjade film-coated tablets should be taken once a day. You should ideally take your Exjade at the same time each day. Exjade film-coated tablets may be taken on an empty stomach or with a light meal.

Option 1



Option 2



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 have taken too much EXJADE, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show the doctor the pack of tablets. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting and kidney or liver problems that can be serious.

How do I take Exjade® (deferasirox) dispersible tablets?

What dose will I take?

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

If you are changing to Exjade dispersible tablets from a different medication (such as deferoxamine), your doctor may choose your Exjade dose based on how much of the previous medication you were taking.

Which tablet(s) will I take?

Exjade dispersible tablets come 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.



125 mg



250 mg



500 mg

Tablets shown actual size.

When will I take Exjade dispersible tablets?

You should take your Exjade dispersible tablets once a day and at the same time each day. Taking Exjade at the same time each day will help you remember when you should take your tablet. Exjade dispersible tablets should be taken on an empty stomach at least 30 minutes before eating.

How do I store Exjade?

You should store your Exjade tablets in their original packaging to protect against moisture.

Steps to take Exjade dispersible tablets



Step 1:

DROP your Exjade dispersible tablet(s) into a glass of orange juice, apple juice, or water. You can also use the Exjade mixer bottle. Make sure that you use the exact amount of liquid directed by your doctor.

Step 2:

STIR until the Exjade tablet(s) completely dissolve. The liquid in the glass will look cloudy and the consistency of the mixture may be thick.

Step 3:

DRINK all of the Exjade mixture immediately. Then add a little water or juice to what is left in the glass, swirl the liquid around and drink that, too.

Do not chew or swallow tablets whole. Do not break or crush the tablets.

Do not dissolve your Exjade dispersible tablets in fizzy drinks or milk.

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 have taken too much Exjade, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show the doctor the pack of tablets. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting and kidney or liver problems that can be serious.

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 doctor may adjust your Exjade dose up or down based on these tests.

Test	Before starting Exjade	Every month	Once per year
Iron Serum ferritin	✓	✓	
Kidneys Serum creatinine	✓ 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	✓		✓
Weight and height	✓		✓
Pediatric patients: Assess body development (eg, your weight, sexual development, and how much you grow per year)	✓		✓

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 kidney problems

Does Exjade have side effects?

Like all medicines, Exjade can have side effects. However, not all patients experience them. The most frequent side effects are mild to moderate and usually go away once you get used to treatment. This can take a few days or weeks.

Common side effects include nausea, vomiting, diarrhea, 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 will be checked regularly during treatment. (See table on previous page.)

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

These side effects are uncommon or rare. Stop taking this medicine and tell your doctor right away if you experience any of the following:

- Severe rash or difficulty breathing and dizziness, or swelling mainly of the face and throat (signs of severe allergic reaction);
- Rash, red skin, blistering of lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes, (signs of severe skin reactions);
- Marked decrease in the amount of urine your body produces (sign of kidney problem);
- Vomiting blood and/or have black stools;
- A combination of drowsiness, upper-right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems);
- If you experience difficulty thinking, remembering information, or solving problems, being less alert or aware or feeling very sleepy with low energy (potential signs of a high level of ammonia in your blood, which may be associated with liver or renal problems and lead to a change in your brain function)
- Frequent abdominal pain, particularly after eating or taking Exjade;
- Severe upper stomach pain;
- Frequent heartburn;
- Partial vision loss

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?

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 (used as a treatment for heart problems and migraines)
- 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)
- Busulfan (used as a treatment prior to transplantation in order to destroy the original bone marrow before the transplant)

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 serum ferritin (SEER-um FAIR-it-in), or **SF**, test. This test 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 dosage

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
- Exjade dispersible tablets

- How many tablets will I take each day?

If 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.
