




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 Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal> and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Exjade to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

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

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - <http://www.medicinesauthority.gov.mt/rmm> - and download the required material with the latest date.

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Introduction: Exjade® (deferasirox) Handbook

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

EXJADE is registered as film-coated tablets and granules in the EU. However, medicines containing deferasirox are also available as film-coated tablets and dispersible tablets marketed under different tradenames as generic alternatives to EXJADE. 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. 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 11). 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.



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 swallowing, Exjade enters your blood and “captures” extra iron available.



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 in the EU, medicines containing deferasirox are registered as film-coated tablets/granules and dispersible tablets marketed under different tradenames as generic alternatives to EXJADE. Switching from Exjade® (deferasirox) dispersible tablets to Exjade film-coated tablets/granules, you will need a lower dose. In case of switch from deferasirox dispersible tablets to EXJADE film-coated tablets/granules, a lower dose than the deferasirox dispersible tablets will have to be taken. Please discuss with your physician. Switching from 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



180 mg



360 mg



Tablets displayed are not 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).

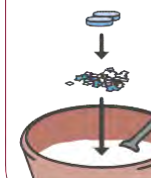
You should immediately and completely consume the entire dose and not store any for future use.

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).

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 and / or plasma cystatin C	✓	✓ 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	✓		✓ for pediatric patients
Pediatric patients: Assess body development (eg, your weight, sexual development, and how much you grow per year)	✓		✓

* For non transfusion dependent patients, Liver iron concentration (LIC) should be monitored every 3 months when serum ferritin is $\leq 800 \mu\text{g/l}$

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 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:

My Exjade dosing regimen

Reduce my SF level to

I am taking

Exjade film-coated tablets

My weight:

- 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.

This educational material is a part of the conditions of the Marketing Authorisation"



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