

My Jadenu[®] (deferasirox) Handbook

NAME _____

DATE _____

Jadenu® (deferasirox) Handbook

This handbook contains important information, including how to take Jadenu the right way, depending on the formulation you have been prescribed. You will learn about monitoring your treatment, possible side effects, and taking other medicines while on Jadenu.

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

Jadenu 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, Jadenu film-coated tablets may be crushed and sprinkled onto soft food.



Tablets displayed are not actual size.

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What is Jadenu® (deferasirox)?

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

Why was I prescribed Jadenu?

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

- Beta thalassemia major
- 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 Jadenu work?

Jadenu works by a process called **“chelation”** (key-lay-shun).

After you have taken Jadenu, it enters your blood and “captures” extra iron it finds.



What is Jadenu used for?

Jadenu is used to treat chronic iron overload caused by frequent blood transfusions (≥ 7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Jadenu 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 (< 7 ml/kg/month of packed red blood cells), in patients with other types of anemias, and in children aged 2 to 5 years.

Jadenu is also used in the treatment of chronic iron overload in patients with non-transfusion dependent thalassemia syndromes aged 10 years and older.

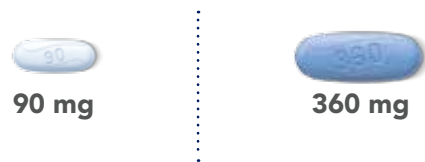
How do I take Jadenu® (deferasirox) film-coated tablets?

What dose will I take?

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

Which tablet(s) will I take?

Jadenu 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.



Tablets shown actual size.

When will I take Jadenu film-coated tablets?

Jadenu 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 Jadenu film-coated tablets

Jadenu film-coated tablets should be swallowed whole with some water. For patients who are unable to swallow whole tablets, the Jadenu 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 Jadenu, 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 Jadenu tablets than I should?

If you take more Jadenu 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 Jadenu® (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 Jadenu	Every month	Once per year
Iron Serum ferritin	✓	✓	
Kidneys Serum creatinine and/or Creatinine clearance	✓ This blood test will be taken twice before starting Jadenu	✓ 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	✓		✓
Pediatric patients: Assess body development (eg, your weight, sexual development, and how much you grow per year)	✓		✓
Weight and height	✓		✓

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

Does Jadenu have side effects?

Like all medicines, Jadenu 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, diarrhea, pain in the abdomen, bloating, constipation, indigestion, rash, and headache.

Your kidney and liver function will be tested before you start Jadenu and you will be monitored 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 straight 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),
- Severe rash, red skin, blistering of lips, eyes or mouth, skin peeling, sore throat (signs of severe skin reaction),
- Marked decrease in your urine output (sign of kidney problem),
- A combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems),
- Vomiting blood and/or have black stools,
- Frequent abdominal pain, particularly after eating or taking Jadenu,
- Severe upper stomach pain (pancreatitis),
- Frequent heartburn,
- Partial vision loss
- Decreased hearing

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.

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

Jadenu® (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 Jadenu® (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 Jadenu
- Antacids (medicines used to treat heartburn) containing aluminum, which should not be taken at the same time as Jadenu
- 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)

My progress with Jadenu

My treatment goal

The goal of Jadenu 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 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 Jadenu 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

Starting Jadenu

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

Date: _____	My current SF level: _____
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My treatment goal is to:

Reduce my SF level to

My weight:

My Jadenu dosing regimen

I am taking

_____ Jadenu **90 mg** tablets each day

_____ Jadenu **360 mg** tablets each day

Jadenu 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.

Notes

Notes



Novartis (Singapore) Pte Ltd
20 Pasir Panjang Road Mapletree Business City
#10-25/28 (West Tower) Singapore 117439
Phone +65 6722 6010 Fax +65 6323 4335
www.novartis.com

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SG2305221982

This document has been approved by HSA on 17-05-2021.