MONITOR YOUR SERUM FERRITIN LEVELS DURING IRON CHELATION THERAPY

KEEPING TRACK OF YOUR LEVELS CAN HELP YOU SPOT AN UPWARD OR DOWNWARD TREND

When your doctor gives you the results of your latest serum ferritin (SF) levels every month, record it here, and circle the red or green arrow below to show whether they have gone up or down since the last visit.

- Consistently high SF levels (greater than 1000 mcg/L) may indicate too much iron in your body
- If after 3-6 months, you start to see a trend in your SF levels, your dose may need to be adjusted

Bring this chart with you to your next doctor appointment, and talk to your doctor about how your therapy is working.

Date	SF Levels	SPOT THE TREND Circle up or down arrow based on your last visit	
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓
		↑	↓

INDICATION

Treatment of Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload)

JADENU® (deferasirox) tablets for oral use and JADENU® Sprinkle (deferasirox) granules are indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.

Limitations on the Use of JADENU

- It is not known if JADENU is safe or effective when taken with another therapy that lowers iron levels in the blood
- Patients who have a serious blood disorder known as myelodysplastic syndromes (MDS) may take JADENU to treat chronically elevated levels of iron in the blood caused by repeated blood transfusions. The iron-lowering effects and safety of JADENU have not been studied in clinical trials specifically designed for just these patients with MDS

Please see additional Important Safety Information, and click here for full Prescribing Information for JADENU® (deferasirox) tablets for oral use and JADENU® Sprinkle (deferasirox) granules, including Boxed WARNING.

JADENU® Sprinkle (deferasirox) granules
90 mg, 180 mg, 360 mg

JADENU® (deferasirox) TABLETS
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IMPORTANT SAFETY INFORMATION for JADENU® (deferasirox) tablets for oral use and JADENU® Sprinkle (deferasirox) granules

What is the most important safety information to know about JADENU?

JADENU contains deferasirox, the same active ingredient in EXJADE® (deferasirox) tablets for oral suspension. Deferasirox may cause serious kidney problems, liver problems, and bleeding in the stomach or intestines. In some cases, these problems were fatal. Kidney problems occurred particularly in patients with multiple medical conditions and those who were very ill because of their disease. Bleeding in the stomach or intestines occurred more often in elderly patients. Liver problems were more likely to happen in patients older than 55 years.

Your doctor should check your kidney function with blood tests and urinalyses:

- Before taking JADENU
- Monthly during treatment

If you already have a history of kidney problems or are at risk for kidney problems, your doctor should check your kidneys:

- Every week for the first month
- Monthly during treatment

Your doctor should check your liver function with blood tests:

- Before taking JADENU
- Every other week for the first month after starting JADENU
- Monthly during treatment

You should not take JADENU if you have:

- Certain kinds of kidney problems
- Preexisting severe liver problems
- High-risk MDS
- Advanced cancer
- Low blood counts (low platelets)
- An allergy to JADENU or any ingredient of JADENU

Additional Important Safety Information

Kidneys

- If you have a preexisting kidney condition, are elderly, have multiple medical conditions, or are taking medicine that affects your kidneys, you are at increased risk of complications. Your doctor will do blood tests (serum creatinine and/or creatinine clearance, estimated glomerular filtration rate (eGFR), and serum electrolytes) every week for the first month you are taking JADENU or if your dose has changed, and then every month after that. Your doctor may adjust your dose based on the results of these tests
- Your doctor will also collect urine samples monthly
- Some patients developed severe kidney problems while taking deferasirox, in some cases fatal, and in some cases requiring dialysis. Most of the fatalities occurred in patients who were very ill because of their disease

In younger patients, stop taking JADENU during serious illnesses which can cause dehydration such as vomiting, diarrhea, or prolonged decreased oral intake.

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IMPORTANT SAFETY INFORMATION for JADENU® (deferasirox) tablets for oral use and JADENU® Sprinkle (deferasirox) granules (continued)

Liver

- If you have a preexisting severe liver problem, you should not use JADENU
- If you have mild or moderate liver problems, your doctor will do blood tests (serum transaminases and bilirubin) before starting treatment, every 2 weeks during the first month of treatment, and then monthly. Your doctor may adjust your dose based on the results of these tests
- Some patients developed severe liver problems, in some cases fatal, while taking deferasirox. Many of these patients were older than 55 years of age and/or had multiple medical conditions already affecting their liver

Bleeding in the Stomach or Intestines

- Some patients developed stomach irritation or bleeds while taking deferasirox. In some cases, stomach bleeds were fatal, usually in patients who were elderly and had preexisting blood cancers and/or low blood counts (low platelets)
- Talk to your doctor if you are taking other drugs that can also irritate your stomach or cause a stomach bleed (eg, pain relievers/anti-inflammatory drugs, corticosteroids, oral bisphosphonates, or blood thinners)

Blood Disorders

- Some patients developed severe blood disorders, in some cases fatal, while on deferasirox therapy. Having a preexisting blood disorder may increase the risk
- Your doctor will do a blood test to check your blood counts

Increased Risks With Different Ages

- *Elderly Patients*: Since deferasirox has been on the market, there have been reports of serious reactions, sometimes leading to death. These serious reactions and deaths have happened most often when deferasirox was taken by elderly patients
- *Pediatric Patients*: Serious and fatal events have occurred in pediatric patients. These were associated with dehydration or when dosing is continued as the iron burden is in the range of normal

Allergic Reactions

- Serious allergic reactions (which include swelling of the throat) have been reported in patients taking deferasirox, usually within the first month of treatment
- If you develop swelling of the throat, a severe rash, hearing problems, or vision disturbances, stop taking JADENU and contact your doctor immediately

Severe Skin Reactions

- Severe skin disorders that result in a very serious rash, called Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and erythema multiforme have been reported during treatment with deferasirox. Other skin reactions including DRESS (drug reaction with eosinophilia and systemic symptoms) can also occur. If you develop a severe rash, stop taking JADENU and contact your doctor immediately
- Mild to moderate skin rashes may occur during treatment with deferasirox. Let your doctor know if the rash doesn't go away on its own or gets worse. Your doctor may need to change your dose of JADENU

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QUESTIONS TO ASK YOUR DOCTOR WHILE TRACKING YOUR PROGRESS

AS YOU CONTINUE TO TRACK YOUR SF LEVELS, HERE ARE SOME QUESTIONS TO DISCUSS WITH YOUR DOCTOR TO HELP YOU BETTER UNDERSTAND WHAT TO EXPECT FROM YOUR TREATMENT AND HOW WELL YOU'RE DOING.

- What should my target SF level be?
- What can I do if my SF levels are not dropping below 1000? Does that mean that I may need a higher dose?
- What happens if my SF levels are staying lower than 500? Do I have to keep taking JADENU?
- When taking JADENU, how quickly will my SF levels start to drop?
- How can I tell if JADENU is working for me?
- What long-term effects can occur if my SF levels do not drop?
- I've been experiencing some side effects. What can I do to manage them? Does my treatment plan need to be adjusted?
- Since starting JADENU, my weight has changed. Will this affect how my treatment works?

IMPORTANT SAFETY INFORMATION for JADENU® (deferasirox) tablets for oral use and JADENU® Sprinkle (deferasirox) granules (continued)

Hearing and Vision Changes

- Changes to hearing and vision have been reported in patients taking deferasirox. If you notice changes in your hearing or eyesight, contact your doctor immediately
- You may also receive a hearing or vision test prior to receiving JADENU, and yearly thereafter. Your doctor may change your dose based on the results of these tests

Common Side Effects

- The most commonly reported side effects related to deferasirox in clinical trials were mainly nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash
- Let your doctor know if you are experiencing any side effects. Your doctor may need to change your dose
- If you experience diarrhea or vomiting, you must continue to drink fluids
- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088

Taking Other Medicines With JADENU

- If you are taking other medicines, such as birth control pills, diabetes drugs, seizure drugs, cholesterol-lowering drugs, or medicine for serious illnesses, talk to your doctor. JADENU may affect how these drugs work

Talk to your doctor to determine if prescription JADENU therapy is right for you.

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NOVARTIS

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