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.
If you have been prescribed JADENU® tablets or JADENU® Sprinkle granules, it means your doctor has determined that you have a condition called Chronic Iron Overload. This booklet will provide information about JADENU and explain how JADENU may help you get control of your Chronic Iron Overload.

If you have had 10 or more Red Blood Cell transfusions, you may be at risk for Chronic Iron Overload. One transfusion, or 2 units of blood, can overload the body with ≥ 100x the normal daily iron intake. Over time, as this excess iron builds up, you can develop Chronic Iron Overload.

**WHY HAS MY DOCTOR PRESCRIBED JADENU FOR ME?**

**IMPACT AND MANAGEMENT OF CHRONIC IRON OVERLOAD**

**CHRONIC IRON OVERLOAD CAN CAUSE ORGAN DAMAGE**

**IF LEFT UNTREATED, IRON CAN BUILD UP IN THE HEART AND LIVER**

**HERE IS SOME IMPORTANT INFORMATION TO KNOW**

- Ferritin is a protein in your cells that stores iron
- An SF test will tell you how much iron is stored in your blood and body
- SF levels greater than 1000 mcg/L may indicate too much iron in your body
- It is important to try and keep your SF levels below 1000 mcg/L

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

**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.

**IMPORTANT SAFETY INFORMATION**

- JADENU contains deferasirox, the same active ingredient in EXJADE® 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

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**JADENU IS SIMPLE TO TAKE ON A ONCE-DAILY BASIS**

**JADENU PROVIDES:**
- A way to remove the excess iron because your body has no natural way to get rid of it
- Convenient administration that fits into your daily schedule and routine
- Two administration options: JADENU® (deferasirox) tablets or JADENU® Sprinkle (deferasirox) granules

**JADENU SIMPLE-TO-TAKE OPTIONS**

**TABLETS**
Swallow the number of tablets prescribed with water or other liquids
- May be taken with or without a light meal
- Take once a day (preferably at the same time each day)
- Take exactly as prescribed by your doctor

**SPRINKLE**
Sprinkle the full dose of granules on soft food (eg, yogurt or applesauce) immediately before use

* Light meals are meals that contain less than 7% fat and about 250 calories. Examples of a light meal include a whole wheat English muffin, a packet of jelly, and skim milk, or a turkey sandwich with 2 ounces of turkey on whole wheat bread with lettuce, tomato, and 1 packet of mustard.

**DO NOT TAKE JADENU WITH ALUMINUM-CONTAINING ANTACID PRODUCTS.**

**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

**SET TREATMENT GOALS AND MILESTONES WITH YOUR DOCTOR**

**TOGETHER WITH YOUR DOCTOR, YOU ARE TRYING TO REACH SF LEVELS OF 1000 MCG/L OR LOWER**
- As you receive your monthly SF levels, record them in your SF Tracker
- Talk to your doctor about which SF levels show milestones in your treatment

**WHY THIS IS IMPORTANT**
By keeping track of SF levels after each transfusion, you will be able to quickly spot an upward or downward trend in iron levels so you can talk to your doctor

After starting JADENU, your doctor will:
- Monitor your SF levels regularly
- Adjust your dose if necessary

- If you’re taking doses of 21 mg per kg and your SF levels remain consistently above 2500 mcg/L (and are not showing signs of decreasing over time), your doctor may consider doses of up to 28 mg per kg. However, doses above 28 mg per kg are not recommended
- If your serum ferritin falls below 1000 mcg/L at 2 consecutive visits, your doctor may reduce your dose, especially if the JADENU dose is greater than 17.5 mg/kg/day
- If your SF level consistently falls below 500 mcg/L, your doctor may consider temporarily interrupting your therapy with JADENU

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

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

**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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**GET ALL THE RESOURCES YOU NEED**

**ONLINE SUPPORT**
- Visit www.jadenu.com for more information
- Sign up to receive information, tips, and resources from Novartis Pharmaceuticals Corporation to help you Take ActiOn at www.jadenu.com/patient-support/sign-up-for-support/

**CO-PAY ASSISTANCE**
You may be eligible for immediate co-pay savings on your next prescription:
- Commercially insured patients pay $10 per month
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year

**Terms and Conditions**
This offer is valid only for those with commercial insurance. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit www.CoPay.NovartisOncology.com or call 1-877-577-7756.

**Patient Instructions**
Present this offer and your insurance card along with a valid prescription at any participating pharmacy or through mail order. Patients with commercial insurance are responsible for $10 for a 30-day supply and Novartis pays up to $15,000 per calendar year. If patient reaches the maximum annual cap per calendar year of $15,000, patient will be responsible for the difference. This offer expires on December 31, 2018. Additional Terms and Conditions may apply.

**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.

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HELP CONTROL CHRONIC IRON OVERLOAD WITH JADENU

A SIMPLE-TO-TAKE OPTION
• Once a day
• Anytime, anywhere
• Fits right into your daily routine
• Available as: JADENU® (deferasirox) tablets or JADENU® Sprinkle (deferasirox) granules

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

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