**INDICATION**

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

JADENU® (deferasirox) tablets 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.

- In these patients, deferasirox lowered the levels of iron in the blood (measured by serum ferritin levels) and liver (measured by liver iron concentration)
- There are ongoing studies to find out how JADENU works over a longer period of time

**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
WHY HAS MY DOCTOR PRESCRIBED JADENU FOR ME?

If you have been prescribed JADENU® (deferasirox) tablets or JADENU® Sprinkle (deferasirox) 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.

IMPORTANT SAFETY INFORMATION for JADENU® (deferasirox) tablets 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 kidneys with a blood test called serum creatinine and/or creatinine clearance:
• 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 with blood tests called serum transaminases and bilirubin:
• Before taking JADENU
• Every other week for the first month after starting JADENU
• Monthly during treatment

IMPORTANT SAFETY INFORMATION (continued)

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

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

CHRONIC IRON OVERLOAD IS A TREATABLE CONDITION.

YOUR DOCTOR SHOULD GIVE YOU A MONTHLY BLOOD TEST THAT MEASURES SERUM FERRITIN (SF) LEVELS.

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 (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 give you a blood test (called serum creatinine and/or creatinine clearance) 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 may 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
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.

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 IS SIMPLE TO TAKE ON A ONCE-DAILY BASIS

JADENU: SIMPLE-TO-TAKE OPTIONS

TABLETS
Swallow the number of tablets prescribed with water or other liquids

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

• 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

DO NOT TAKE JADENU WITH ALUMINUM-CONTAINING ANTACID PRODUCTS.

IMPORTANT SAFETY INFORMATION (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 give you blood tests called 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

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 overtime), your doctor may consider doses of up to 28 mg per kg. However, doses above 28 mg per kg are not recommended
• If your SF level consistently falls below 500 mcg/L, your doctor may consider temporarily interrupting your therapy with JADENU

IMPORTANT SAFETY INFORMATION (continued)
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, 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 give you a blood test to check your blood counts

Increased Risks When Used in 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
IMPORTANT SAFETY INFORMATION (continued)

**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

**Serious 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

**COMMON SIDE EFFECTS**
- Nausea
- Vomiting
- Diarrhea
- Stomach pain
- Changes in kidney function
- Skin rash

* These are not all of the side effects that are possible, but they are the most common ones experienced.

**TALK TO YOUR DOCTOR IF YOU EXPERIENCE ANY SIDE EFFECTS**
- If you experience side effects, your doctor may decide to adjust your dose, or take you off the medicine

**TIPS AND TOOLS TO GET THE MOST OUT OF JADENU**

Partnering with your doctor can help you stay on top of your JADENU tablets and JADENU® Sprinkle (deferasirox) granules therapy. Here are some helpful tips:

- **To help you remember to take your medicine:**
  - Organize your medication at the beginning of each week
  - Set an alarm at the same time every day as a reminder
  - Include as part of your daily calendar
  - Take your medication at the same time you brush your teeth every day

- **To help you take your medication no matter where you go:**
  - Always travel with your medication handy (never leave medication in luggage that will be checked when flying)
  - Bring a bottle of water or soft food (eg yogurt or applesauce) with you when leaving the house

- **To help with any questions you may have about your medicine:**
  - Keep the phone number of your doctor’s office programmed in your phone
  - Take advantage of the JADENU Clinical Educator program and keep the phone number on hand
  - Connect with your pharmacy early so that your next shipment of JADENU can be delivered on time

- **To help track your SF levels:**
  - Talk to your doctor, and see if the office has an online patient portal where you can view your monthly lab results
  - Figure out the best way to track your SF levels. There are many different tools out there, but use what works for you. The point is—it’s important to monitor regularly

Please see additional Important Safety Information, and click here for full Prescribing Information for JADENU® (deferasirox) tablets and JADENU® Sprinkle (deferasirox) granules, including Boxed WARNING.
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. Not valid for cash payments, where product is not covered by patient’s commercial insurance, or where plan reimburses you for entire cost of your prescription drug. Offer is not valid where prohibited by law. Valid only in the United States and Puerto Rico. This program is not health insurance. Offer may not be combined with any other rebate, coupon, or offer. The card is the property of Novartis Pharmaceuticals Corporation and must be returned upon request. Novartis reserves the right to rescind, revoke, or amend the program without notice. Patient certifies responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting receipt of program rewards, if necessary, to any commercial insurer. This offer expires on December 31, 2017. Additional Terms and Conditions may apply.

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 per month and Novartis will pay the remaining co-pay, up to $15,000 per calendar year. Limitations apply. Offer is 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. Patient certifies responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting receipt of program rewards, if necessary, to any commercial insurer. This offer expires on December 31, 2017. Additional Terms and Conditions may apply.

IMPORTANT SAFETY INFORMATION (continued)
Common Side Effects (continued)
• 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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