IMPORTANT SAFETY INFORMATION for JADENU (deferasirox) Tablets

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
• 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 • Monthly during treatment

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
• There are patients with a serious blood disorder known as myelodysplastic syndromes (MDS) that 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

INDICATION

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

JADENU™ (deferasirox) tablets is 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

Please see additional Important Safety Information throughout, and accompanying full Prescribing Information.
UNDERSTANDING CHRONIC IRON OVERLOAD

HOW DOES CHRONIC IO AFFECT YOU?
- Multiple blood transfusions may put you at risk for chronic IO
- Blood diseases that may require transfusions include:
  - Sickle cell disease
  - Thalassemia
  - Myelodysplastic syndromes (MDS)
  - Other anemias

HOW CAN YOU TELL IF YOU HAVE CHRONIC IO?
- Symptoms are hard to see
- Tracking serum ferritin levels monthly will help determine if you have chronic IO
- Ferritin is a protein in your cells that stores iron
- Consistently high serum ferritin levels may indicate that there is too much iron in your body
- Your doctor may prescribe iron chelation therapy such as JADENU™ (deferasirox) tablets
- Before starting treatment with JADENU, your doctor will order tests to check kidney and liver function, as well as your eyesight and hearing

WHY IS IRON CHELATION IMPORTANT?
- Iron chelation is:
  - A process that helps get rid of extra iron that has built up in your body
  - Usually a long-term treatment
  - It may take several months for your iron levels to go down

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JADENU: SIMPLE-TO-TAKE TABLETS

TREATMENT PREPARATION

• JADENU tablets should be swallowed once daily with water or other liquids, preferably at the same time each day
• Light meals are meals that contain less than 7% fat and ~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 oz. of turkey on whole wheat bread with lettuce, tomato, and one packet of mustard
• JADENU offers convenient administration for your IO treatment that fits into your daily routine
  —Your doctor will calculate the dose you need and tell you how many tablets to take each day
  —After starting therapy, your doctor will monitor your serum ferritin monthly and adjust your dose if necessary

REMEMBER, WHEN TAKING JADENU:

Aluminum-containing antacids should not be taken at the same time

Doses are based on how much you weigh. Keep your doctor informed of any weight changes, as your dose may need to be adjusted if you gain or lose weight

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout, including Boxed WARNING on the front cover, and accompanying full Prescribing Information.
Both prescription JADENU™ (deferasirox) tablets and EXJADE® (deferasirox) tablets for oral suspension are to be taken once daily, preferably at the same time every day. If you are currently taking EXJADE and you and your doctor have decided to switch to JADENU, here are some things you should know.

**EXJADE**
- Take on an empty stomach
- Take the exact amount of medication prescribed
- Measure 8 oz of water or apple or orange juice
- Stir or mix the tablets
- Drink mixture
- After swallowing drink, remix any leftover residue and drink again
- Wait 30 minutes before eating

**JADENU**
- Take with or without a light meal (containing less than 7% fat and ~250 calories)
- Swallow with some water or liquid
- Take the exact number of tablets prescribed

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**IMPORTANT SAFETY INFORMATION (cont)**

**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 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

**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

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**DOSE CONVERSION FROM EXJADE TO JADENU**

- JADENU™ (deferasirox) tablets and EXJADE® (deferasirox) tablets for oral suspension are made from the same active ingredient.
- JADENU tablet strengths are less than EXJADE tablet strengths—this does not mean that one works better than the other.

### EXJADE DOSE STRENGTHS*:

- **125 mg**
- **250 mg**
- **500 mg**

### JADENU DOSE STRENGTHS*:

- **90 mg**
- **180 mg**
- **360 mg**

*These pills are not actual size.

- For patients who have trouble swallowing JADENU tablets, EXJADE should be considered (see EXJADE Prescribing Information). EXJADE and JADENU are not interchangeable. If you have switched to JADENU, discontinue use of EXJADE and properly dispose of any leftover medication.

### IMPORTANT SAFETY INFORMATION (cont)

#### 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.

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SIDE EFFECTS

Studies evaluating the side effects of JADENU™ (deferasirox) tablets are ongoing. However, there are side effects associated with deferasirox, the active ingredient in JADENU.

**COMMON SIDE EFFECTS INCLUDE:**

- **Skin rash**  
  —Mild to moderate rashes often resolve spontaneously. Interrupt treatment with JADENU in severe cases. Starting again at low doses while taking an oral steroid for a short time may be considered.

- **Nausea**
- **Vomiting**
- **Diarrhea**
- **Stomach pain**

- **Changes in kidney function**

**IMPORTANT SAFETY INFORMATION (cont)**

**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.

**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.
KNOW WHAT TO EXPECT

Partnering with your doctor can help you stay on top of your therapy

HERE ARE SOME TIPS TO HELP YOU STAY ON TRACK:

To help you remember to take your medication:
- Organize your medication using a pill box 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

To help you take your medication no matter where you go:
- Always travel with your medication/pill box handy (never leave medication in luggage that will be checked when flying)
- Bring a bottle of water 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™ (deferasirox) tablets 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

IMPORTANT SAFETY INFORMATION (cont)
Serious Skin Reactions
- Severe skin disorders that result in a very serious rash, called Stevens-Johnson syndrome and erythema multiforme, have been reported during treatment with deferasirox. 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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SUPPORT TO HELP YOU GET JADENU AND STAY ON TRACK

ONLINE SUPPORT

• Visit www.jadenu.com for more information about chronic IO and JADENU™ (deferasirox) tablets
• Discover tips, tools, and other resources designed to help you

YOU MAY BE ELIGIBLE FOR A $0 CO-PAY*

Co-pay Assistance
• If you are commercially insured, you may be eligible for a $0 co-pay
• Novartis will pay the full co-pay, up to a maximum of $20,000 per calendar year
• Your specialty pharmacy will process the $0 co-pay when your prescription is filled

PATIENT ASSISTANCE NOW ONCOLOGY (PANO)

• Novartis is committed to helping patients receive the medicines they need
• PANO offers quick and easy access to information about the different kinds of support and reimbursement programs available
• Call PANO at 1-800-282-7630

Terms & Conditions:
*Valid only for those with commercial insurance. Not valid for cash paying patients or where drug is not covered by the primary insurance. Offer not valid under Medicare, Medicaid, or any other federal or state program, or where plan reimburses you for entire cost of your prescription drug. Offer is not valid where prohibited by law. Valid only in the US and Puerto Rico. This program is not health insurance. Offer may not be combined with any other rebate, coupon, or offer. 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, 2015.

IMPORTANT SAFETY INFORMATION (cont)

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

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HAVE QUESTIONS? ANSWERS ARE A PHONE CALL AWAY

Our Clinical Educators are available face-to-face or over the phone to answer your questions about JADENU™ (deferasirox) tablets

Novartis offers:
• One-on-one counseling sessions
• For more information, call 1-877-988-8812

TREATMENT DELIVERY MADE SIMPLE

JADENU is available at specialty pharmacies nationwide and select in-office and hospital pharmacies.

Your doctor submits your prescription and any necessary paperwork

The specialty pharmacy calls you to confirm your prescription, and your prescription goes out for delivery

You receive your prescription in the mail

IMPORTANT SAFETY INFORMATION (cont)

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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JADENU™ (deferasirox)

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