NOVARTIS

JADENU

(deferasirox)

180 and 360 mg film-coated tablets

Patient Information Leaflet

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SCHEDULING STATUS: S4

PRODUCT NAME:

JADENU 180 mg film-coated tablets

JADENU 360 mg film-coated tablets

Deferasirox

Sugar free

Read all of this leaflet carefully before you or your child start taking JADENU

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare providers**
- **JADENU has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

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2. What you need to know before you take JADENU

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1. WHAT JADENU IS AND WHAT IT IS USED FOR

JADENU contains an active substance called deferasirox. It is an iron chelator used to remove the excess iron from the body tissues.

JADENU is used for transfusional iron overload (excess amount of iron in patients receiving regular blood transfusions). JADENU is used to treat iron overload caused by blood transfusions.

JADENU is used for non-transfusion-dependent thalassaemia syndromes (excess iron in patients with thalassaemia who are not receiving regular blood transfusions).

How JADENU works

- Blood transfusions may be necessary in patients suffering from certain types of anaemia such as thalassaemia, sickle cell disease or myelodysplastic syndromes. However, repeated blood transfusions can cause iron overload. Over time, iron overload can damage important organs such as the liver and heart. The body has no effective way to remove iron.
- Medicines called iron chelators are therefore used in patients with this iron overload to remove the excess iron and prevent iron-induced organ damage. JADENU attaches itself to the excess iron and forms a complex with the iron which is then eliminated mainly through the stools.

You will have regular blood tests to monitor the amount of iron in your body (level of ferritin, liver and/or cardiac iron content) in order to evaluate how well JADENU is working. Your doctor will take these tests into consideration when deciding on the dose of JADENU most suitable for you and will also use these tests to decide when you should stop taking JADENU.

If you have any questions about how JADENU works or why this medicine has been prescribed for you, ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE JADENU

Do not take JADENU:

- If you are hypersensitive (allergic) to deferasirox or any of the other ingredients of JADENU listed in this leaflet.
- If you have a kidney problem.
- If you use Repaglinide, a medicine used in diabetes.
- If you have high risk myelodysplastic syndrome (MDS).
- If you have other blood disorders.
- If you have severe liver disease
- If you are pregnant or are breastfeeding your baby.

If this applies to you, tell your doctor before taking JADENU. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions:

Take special care with JADENU

- If you have a mild to moderate liver problem.
- If you are taking anti-inflammatory medication (NSAIDs) as it may increase the risk of gastrointestinal complications.
- Extra caution should be used in elderly patients as they may experience side effects more frequently.
- Blood tests to monitor the amount of ferritin should be done regularly.

If any of these apply to you, tell your doctor.

Taking JADENU with food

JADENU should be swallowed whole with some water. For patients who are unable to swallow whole tablets, JADENU film-coated tablets may be crushed and administered by sprinkling the full dose on soft food like yogurt or apple sauce (apple puree). The dose should be immediately and completely consumed, and not stored for future use. JADENU 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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking JADENU.

The effect of JADENU on human fertility is not known.

Pregnancy

JADENU is not to be used during pregnancy. If you are pregnant or think you may be, tell your doctor before taking JADENU. Your doctor will discuss with you the potential risk of taking JADENU during pregnancy.

Breastfeeding mothers

Breastfeeding is not recommended during treatment with JADENU. Tell your doctor if you are breastfeeding your infant.

Driving and using machines

If you feel dizzy after taking JADENU, do not drive or operate any tools or machines until you are feeling normal again.

Taking other medicines with JADENU

Always tell your healthcare professional if you are taking any other medicine, including complementary medicines.

Before you take JADENU, tell your doctor, pharmacist or healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because these might interact with JADENU. This includes, in particular:

- If you are taking medicines on a regular basis, including complementary or traditional medicines, the concomitant use of JADENU may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.
- Antacids (medicines used to treat heartburn) containing aluminium should not be taken at the same time as JADENU.
- Anti-inflammatory medication may increase the risk of gastrointestinal complications.
- Theophylline (used to treat respiratory diseases such as asthma).
- Busulfan (used as treatment prior to bone marrow transplant).

Your doctor may need to test the level of some of these medicines in your blood. Your doctor will take these tests into consideration when deciding on the most suitable dose of these medicines for you.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

3. HOW TO TAKE JADENU

Always take JADENU exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

How much JADENU to take

- JADENU can be used to treat adults, adolescents and children aged 2 years and over. The dose of JADENU is related to body weight for all patients. Your doctor will tell you how many tablets to take.
- The usual daily dose of JADENU at the start of the treatment is 14 mg per kilogram body weight for patients receiving regular blood transfusions.
- 7 mg per kilogram body weight for patients not receiving regular blood transfusions.
- A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs. Depending on how you respond to treatment, your doctor may later adjust your treatment to a higher or lower dose.

When and how to take JADENU

Take JADENU:

- Whole, with some water.

- Once a day, every day, at about the same time each day, on an empty stomach or with a light meal.
- For patients who are unable to swallow whole tablets, JADENU film-coated tablets may be crushed and administered by sprinkling the full dose on soft food like yogurt or apple sauce (apple puree).
- Taking JADENU at the same time each day will help you remember when to take your tablets.
- Do not use any other fruit juices, sparkling drinks or milk to dissolve the tablets.
- Do not chew or split the tablets.

How long to take JADENU

It is important to take JADENU every day and continue your treatment exactly as prescribed. Your doctor will regularly monitor your condition to check that JADENU is having the desired effect.

If you take more JADENU than you should

If you have taken too much JADENU, or if someone else accidentally takes your tablets, go to your doctor or hospital for advice straight away. Show the doctor the pack of tablets. Medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting, and kidney or liver problems that can be serious.

If you forget to take JADENU

If you miss a dose, take it as soon as you remember on that day. Take your next dose as scheduled. Do not take a double dose on the next day to make up for the forgotten tablet.

Effects when treatment with JADENU is stopped

Do not stop taking JADENU unless your doctor tells you to. If you stop taking JADENU, the excess iron will no longer be removed from your body.

4. POSSIBLE SIDE EFFECTS

JADENU can have side effects.

Some side effects could be serious.

If you experience any of these side effects, **stop taking the medicine and tell your doctor immediately** or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to JADENU. You may need urgent medical attention or hospitalization.

These side effects are frequent

- If you notice a severely decreased urine output (sign of kidney problem).
- If you experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).
- If you vomit blood and/or have black stools.
- If you experience frequent abdominal pain (ulcers) particularly after eating or taking JADENU.
- If you experience frequent heartburn.
- If you experience partial loss of vision.
- If you experience a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (signs of severe skin reaction), Steven Johnson Syndrome.
- Skin rashes may appear during treatment.
- Hypersensitivity reactions such as angioedema and anaphylaxis may occur during treatment.
- Vision and hearing may be impaired.
- Blood disorders may arise.
- Severe upper stomach pain (pancreatitis).

Other side effects are less frequent

If the following side effects affect you severely, tell your doctor:

- Dizziness

- Fever
- Blurred or cloudy vision
- Hearing disturbances
- Sore throat
- Swelling of arms or legs
- Change in the colour of the skin
- Anxiety
- Sleep disorder
- Tiredness

Side effects with frequency not know:

- Hair loss
- A decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anaemia aggravated), and in the number of white blood cells (neutropenia)

Some side effects are serious.

These side effects are less frequent. If any of the following happen, tell your doctor as soon as possible:

- Skin rashes may appear during treatment.
- Hypersensitivity reactions may also occur during treatment.
- Vision and hearing may also be affected.

- Blood disorders may arise.
- Protein in urine.

You will have some blood tests while taking JADENU. Your doctor will look for any changes in the kidney function (level of creatinine) or liver function (level of transaminases).

Your doctor may also want to test your eyesight and hearing while you are taking JADENU.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE JADENU

- Do not use after the expiry date stated on the carton.
- Store at or below 30 °C.
- Store in the original package in order to protect from moisture.
- Do not store JADENU in the bathroom.
- Keep out of the reach and sight of children.
- Do not use any JADENU pack that is damaged or shows signs of tampering.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active substance of JADENU is deferasirox.

The other inactive ingredients are microcrystalline cellulose, crospovidone, povidone K30, magnesium stearate, colloidal silicon dioxide, poloxamer 188, hypromellose, titanium dioxide (E 171), polyethylene glycol 4000, talc, FD&C blue #2/Indigo carminine aluminium lake (E132).
JADENU is supplied as film-coated tablets. Each tablet contains 180 or 360 mg deferasirox. The tablets are not to be divided.

JADENU comes in packs of 30 film-coated tablets in blisters composed of a colourless, transparent laminated plastic film made of PVC/PVDC film with an aluminium foil backing, or a PA/AL/PVC (polyamide/aluminium /polyvinylchloride) film with an aluminium foil backing.

IDENTIFICATION OF JADENU

JADENU® 180 mg: Medium blue, ovaloid, biconvex film-coated tablet with bevelled edges, "NVR" imprinted on one side and "180" on a slight upward slope in between two debossed curved lines on the other side.

JADENU®360 mg: Dark blue, ovaloid, biconvex film-coated tablet with bevelled edges, "NVR" imprinted on one side and "360" on a slight upward slope in between two debossed curved lines on the other side.

HOLDER OF CERTIFICATE OF REGISTRATION

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