Jadenu™ Frequently Asked Questions

1) What is Jadenu?

Jadenu (deferasirox) tablets are an oral iron chelation therapy that treats chronic iron overload due to blood transfusions and chronic iron overload in non-transfusion-dependent thalassemia syndromes (NTDT). Jadenu contains the same active ingredient as Exjade® (deferasirox) tablets for oral suspension. Chronic iron overload develops when the body's limited iron storage capacities are exceeded. Since there is no natural mechanism to remove excess iron from the body, iron builds up – first in the liver, and eventually in the heart[1].

Jadenu is approved under accelerated approval based on a reduction of liver iron concentrations and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2) How does Jadenu work and how is it administered?

Jadenu is administered as once-daily oral tablets. It works by attaching to iron which may be stored in different parts of the body, such as the liver and heart, and removes it through the stool. The Jadenu iron complex leaves the body through the digestive system[2]. Removing iron from the body in this way is called chelation. Chelation happens gradually and Jadenu removes a small amount of iron every day, causing iron levels to decrease over time[2].

3) Why did Novartis change the formulation of deferasirox?

Jadenu contains deferasirox, the same active ingredient as Exjade. Novartis developed this new formulation of deferasirox to help improve patient adherence to iron chelation therapy. The Jadenu formulation has been in development for eight years due to the many steps required to create a once-daily oral chelation therapy that is equivalent to Exjade and can be swallowed whole as tablets. The original formulation used in Exjade requires the patient to mix and drink the medication in a large glass of water or juice on an empty stomach. Jadenu contains the same active ingredient as Exjade in a formulation that can be taken in a single step and may be taken with a light meal, simplifying administration for patients and providing effective reduction of iron overload.

4) How is Jadenu different from Exjade?

Jadenu is a once-daily oral tablet that can be swallowed whole, with water or other liquid, and does not require dispersion in liquid like Exjade, offering a single-step treatment option. This means it can be taken without time-consuming preparation. Jadenu can also be taken with or without a light meal, while Exjade must be taken on an empty stomach.

The dosage strengths of Exjade and Jadenu also differ. Jadenu is available by prescription in three strengths: 90 mg, 180 mg and 360 mg, while Exjade comes in 125

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mg, 250 mg, and 500 mg dosage strengths. Because of the degree of absorption, the dose is lower than Exjade to achieve comparable levels of the drug in the body. For example, the 500 mg dose of Exjade is equivalent to the 360 mg dose of Jadenu.

5) Why are different dosage strengths available?

Jadenu is available by prescription in 90 mg, 180 mg and 360 mg tablets. Multiple dosage strengths allow for dose adjustments based on weight and the levels of iron in the body. Healthcare providers are able to prescribe an appropriate dose of medication for each patient based on considerations of efficacy and safety.

6) Who should take Jadenu?

Jadenu is indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients ages 2 years and older. This indication is approved under accelerated approval based on a reduction of liver iron concentrations and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Jadenu is also indicated to treat patients ages 10 years and older who have chronic iron overload resulting from NTDT and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight and a serum ferritin greater than 300 mcg/L. This indication is approved under accelerated approval based on a reduction of liver iron concentrations (to less than 5 mg Fe/g dw) and serum ferritin levels.

7) Will prescription Exjade still be available?

Exjade will continue to be available to treat patients with chronic iron overload for the near future.

8) How will Jadenu be distributed?

Jadenu will be available through a large number of specialty pharmacies across the country, and also will be dispensed through in-office pharmacies and hospitals.

9) What if a person prescribed Jadenu cannot swallow a tablet?

Exjade, which is dispersed in liquid, is still available for patients who cannot swallow a tablet.

10) Is Jadenu currently approved in any other countries for the treatment of chronic iron overload?

Jadenu was approved in the US and is being submitted for regulatory review in many countries around the world.

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JADENU™
(deferasirox) TABLETS
90 mg, 180 mg, 360 mg

About Jadenu (deferasirox) Tablets for Oral Use

Jadenu is an iron chelator indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients ages 2 years and older. Jadenu is also indicated to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT). These indications are approved under accelerated approval based on a reduction of iron levels in the liver (measured by liver iron concentration) and blood (measured by serum ferritin levels). Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. There are ongoing studies to find out how Jadenu works over a longer period of time.

It is not known if Jadenu is safe or effective when taken with other iron chelation therapy. Controlled clinical trials of deferasirox in patients with myelodysplastic syndromes (a serious blood disorder) and chronic iron overload due to blood transfusions have not been performed.

In the United States, Jadenu is available by prescription only.

Important Safety Information about Jadenu (deferasirox) Tablets for Oral Use

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.

Jadenu should not be taken by patients with pre-existing severe kidney and liver problems; high-risk myelodysplastic syndromes; advanced cancer; low platelet counts; or an allergy to Jadenu.

Since deferasirox has been on the market, there have been reports of serious reactions, sometimes leading to death. Severe blood disorders (including neutropenia, agranulocytosis, worsening anemia and thrombocytopenia), serious allergic reactions (including swelling of the throat), severe skin reactions (including Stevens Johnson syndrome and erythema multiforme), decreased hearing and vision changes have been reported. These serious reactions and deaths have happened most often when deferasirox was taken by elderly patients. The most commonly reported side effects related to deferasirox in clinical trials were nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash.

Please see full Prescribing Information including Boxed WARNING available at www.jadenu.com.

About Exjade (deferasirox) Tablets for Oral Suspension

Exjade is an iron chelator indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients ages 2 years and older. Exjade is also indicated to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT). In patients Exjade lowered the levels of iron in the blood (measured by serum ferritin levels) and liver (measured by liver iron concentration). An improvement in survival or disease symptoms resulting from reduction in elevated iron levels, however, has not been proven.

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It is not known if deferasirox is safe or effective when taken with other iron chelation therapy. Controlled clinical trials of Exjade in patients with myelodysplastic syndromes (a serious blood disorder) and chronic iron overload due to blood transfusions have not been performed.
In the United States, Exjade is available by prescription only.

Important Safety Information about Exjade (deferasirox) Tablets for Oral Suspension

Exjade 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.

Exjade should not be taken by patients with pre-existing severe kidney and liver problems; high-risk myelodysplastic syndromes; advanced cancer; low platelet counts; or an allergy to Exjade.

Since Exjade has been on the market, there have been reports of serious reactions, sometimes leading to death. Severe blood disorders (including neutropenia, agranulocytosis, worsening anemia and thrombocytopenia), serious allergic reactions (including swelling of the throat), severe skin reactions (including Stevens Johnson syndrome and erythema multiforme), decreased hearing and vision changes have been reported. These serious reactions and deaths have happened most often when Exjade was taken by elderly patients. The most commonly reported side effects related to Exjade in clinical trials were nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash.

Please see full Prescribing Information including Boxed WARNING available at www.exjade.com.

References

1. Shander A, Cappellini MD, Goodnough LT. Iron overload and toxicity: the hidden risk of multiple blood transfusions. *Vox Sanguinis*. 2009; 97, 185-197.
2. Deferasirox. National Institutes of Health MedlinePlus website. http://www.nlm.nih.gov/medlineplus/druginfo/meds/a606002.html. Updated on October 1, 2010. Accessed on January 5, 2015.

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