

## Jadenu™ Backgrounder

### About Jadenu

Jadenu (deferiasirox) tablets are an iron chelation therapy indicated for the treatment of chronic iron overload due to blood transfusions and chronic iron overload in non-transfusion-dependent thalassemia syndromes.

Jadenu is available by prescription as once-a-day oral tablets in three strengths: 90 mg, 180 mg and 360 mg, to allow dose adjustments based on weight and the levels of iron in the body. Unlike Exjade® (deferiasirox) tablets for oral suspension, which requires dispersion in liquid, Jadenu tablets can be swallowed whole. Jadenu contains the same active ingredient as Exjade.



Jadenu is available in 90 mg, 180 mg and 360 mg tablets

### How It Works

Jadenu is a tablet that can be taken with or without a light meal, unlike Exjade, which must be taken on an empty stomach. Jadenu works by attaching to iron which may be stored in different parts of the body, such as the liver, and removes it through the stool. Removing iron from the body in this way is called chelation. Jadenu removes a small amount of iron every day, causing iron levels to decrease over time.

It is important for a doctor to monitor levels of iron in the liver and blood on a regular basis, and kidney and liver function on a monthly basis, and adjust the dose based on a patient's test results and prescribing information. Patients should continue taking Jadenu unless directed otherwise by their doctors.

### Who Should Take Jadenu?

Diseases such as sickle cell disease, thalassemia and myelodysplastic syndromes sometimes require blood transfusions<sup>1,2</sup>. Blood transfusions can cause iron to build up in the body, leading to chronic iron overload and causing complications<sup>1,2</sup>.

Jadenu is prescribed for patients with transfusional iron overload who:

- Have iron levels consistently higher than 1,000 micrograms per liter as measured by serum ferritin tests
- Have had a total of 10 or more blood transfusions (or 20 transfused units of blood) over time, which causes iron to accumulate in the body

### Common Side Effects

The most common side effects of deferiasirox in Exjade clinical trials included:

- Nausea
- Vomiting
- Stomach pain
- Diarrhea
- Rash
- Increased kidney laboratory values

Visit [www.jadenu.com](http://www.jadenu.com) for more information

### **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](http://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.

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](http://www.exjade.com).

### **References**

1. Andrews NC. Disorders of iron metabolism. *New England Journal of Medicine*. 1999; 341:1986-1995.
2. Shander A, Cappellini MD, Goodnough LT. Iron overload and toxicity: the hidden risk of multiple blood transfusions. *Vox Sanguinis*. 2009; 97, 185-197.