EMA/515414/2019
EMEA/H/C/005014

Deferasirox Mylan (*deferasirox*)

An overview of Deferasirox Mylan and why it is authorised in the EU

What is Deferasirox Mylan and what is it used for?

Deferasirox Mylan is a medicine used to treat chronic iron overload (an excess of iron in the body) in:

- patients from 6 years of age who have beta thalassaemia major (an inherited blood disorder in which patients do not have enough normal haemoglobin - the protein that carries oxygen around the body - in the blood) and who receive frequent blood transfusions;
- children aged 2 to 5 years with beta thalassaemia major who receive frequent blood transfusions, when deferoxamine (another medicine used to treat iron overload) cannot be used or is inadequate;
- patients from 2 years of age with beta thalassaemia major who receive infrequent blood transfusions, when deferoxamine cannot be used or is inadequate;
- patients from 2 years of age who suffer from other types of anaemia (low levels of haemoglobin in the blood) and who receive blood transfusions, when deferoxamine cannot be used or is inadequate;
- patients from 10 years of age with non-transfusion-dependent thalassaemia syndromes, when deferoxamine cannot be used or is inadequate. Non-transfusion-dependent thalassaemia syndromes are blood disorders similar to beta thalassaemia major but which do not require blood transfusions. In these patients iron overload is caused by excess absorption of iron from the gut.

Deferasirox Mylan contains the active substance deferasirox and is a 'generic medicine'. This means that Deferasirox Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Exjade. For more information on generic medicines, see the question-and-answer document here.

How is Deferasirox Mylan used?

Deferasirox Mylan can only be obtained with a prescription and treatment should be started and supervised by a doctor who is experienced in the treatment of chronic iron overload.

Deferasirox Mylan is available as film-coated tablets (90 mg, 180 mg and 360 mg), to be taken once a day at around the same time.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The starting dose of Deferasirox Mylan depends on the patient's body weight, what the medicine is used for, and on the level of iron overload. The dose is then adjusted as needed, every 3 to 6 months, according to the iron levels in the blood.

For more information about using Deferasirox Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Deferasirox Mylan work?

When the body cannot remove iron effectively, the excess iron can cause damage. The active substance in Deferasirox Mylan, deferasirox, is an 'iron chelator'. It attaches to excess iron in the body to form a compound called a 'chelate' that can be removed by the body, mainly in the stool. This helps to correct the iron overload and prevent damage to organs such as the heart or liver from excess iron.

How has Deferasirox Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Exjade, and do not need to be repeated for Deferasirox Mylan.

As for every medicine, the company provided studies on the quality of Deferasirox Mylan. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Deferasirox Mylan?

Because Deferasirox Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Deferasirox Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Deferasirox Mylan has been shown to have comparable quality and to be bioequivalent to Exjade. Therefore, the Agency's view was that, as for Exjade, the benefits of Deferasirox Mylan outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Deferasirox Mylan?

The company that markets Deferasirox Mylan must issue an education pack to healthcare professionals. This pack aims to inform them about the treatment recommendations with Deferasirox Mylan, including choosing the right dose and the need to monitor the patient's health, especially kidney function. The company will also prepare a similar pack for patients.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Deferasirox Mylan have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Deferasirox Mylan are continuously monitored. Side effects reported with Deferasirox Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Deferasirox Mylan

Deferasirox Mylan received a marketing authorisation valid throughout the EU on 26 September 2019.

Further information on Deferasirox Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/deferasirox-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2019.