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Deferiprone Lipomed (*deferiprone*)

An overview of Deferiprone Lipomed and why it is authorised in the EU

What is Deferiprone Lipomed and what is it used for?

Deferiprone Lipomed is an 'iron chelator' (a substance that attaches to iron) that is used to treat iron overload (an excess of iron in the body) in patients with thalassaemia major. This is an inherited disease in which patients are unable to make enough haemoglobin, the protein found in red blood cells that carries oxygen around the body.

Deferiprone Lipomed is used:

- on its own, when standard iron chelator treatment cannot be used or is inadequate;
- in combination with another iron chelator, when treatment with one iron chelator on its own is ineffective or when prevention or treatment of life-threatening conditions requires rapid or intensive correction of iron levels.

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

How is Deferiprone Lipomed used?

Deferiprone Lipomed can only be obtained with a prescription and treatment should be started and maintained by a doctor who has experience in the treatment of patients with thalassaemia.

Deferiprone Lipomed is available as 500 mg tablets to be taken by mouth. The usual dose of Deferiprone Lipomed is 75 mg per kilogram body weight each day, divided into three separate doses. Doses above 100 mg/kg a day are not recommended because of a potentially increased risk of side effects. The doctor may adjust the dose of Deferiprone Lipomed depending on the patient's response, which should be measured every two to three months with blood tests. The doctor may interrupt treatment if iron levels in the body get too low.

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

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How does Deferiprone Lipomed work?

Patients with thalassaemia major need frequent blood transfusions. When patients receive repeated transfusions, the transfused red cells bring iron into the body. However, the body does not have a natural way of removing excess iron, so it builds up. Over time, the excess iron can damage important organs such as the heart or liver. The active substance in Deferiprone Lipomed, deferiprone, is an iron chelator. It attaches to iron in the body to form a compound that can be excreted by the body, mainly in the urine, and to a lesser extent in the stools. This helps to correct the iron overload and prevent damage due to excess iron.

How has Deferiprone Lipomed 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, Ferriprox, and do not need to be repeated for Deferiprone Lipomed.

As for every medicine, the company provided studies on the quality of Deferiprone Lipomed. 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 Deferiprone Lipomed?

Because Deferiprone Lipomed 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 Deferiprone Lipomed authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Deferiprone Lipomed has been shown to have comparable quality and to be bioequivalent to Ferriprox. Therefore, the Agency's view was that, as for Ferriprox, the benefit of Deferiprone Lipomed outweighs the identified risk and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Deferiprone Lipomed?

The company that markets Deferiprone Lipomed will ensure that patients taking the medicine, or their carers, are provided with a reminder card with information on how to take the medicine safely.

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

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

Other information about Deferiprone Lipomed

Deferiprone Lipomed received a marketing authorisation valid throughout the EU on 20 September 2018.

Further information on Deferiprone Lipomed can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2018.