EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2023
EMA/142149/2023
EMEA/H/C/005974

Withdrawal of application for the marketing authorisation of Feraheme (ferumoxytol)

Covis Pharma Europe B.V. withdrew its application for a marketing authorisation of Feraheme for the treatment of anaemia caused by lack of iron.

The company withdrew the application on 9 March 2023.

What is Feraheme and what was it intended to be used for?

Feraheme was developed for the treatment of iron deficiency anaemia (IDA, when a lack of iron in the body leads to low levels of haemoglobin and red blood cells) in patients who cannot take iron supplements by mouth or for whom iron supplements do not work well enough. It was also intended for use by patients with IDA due to chronic kidney disease, as these patients may not produce enough red blood cells.

Feraheme contains the active substance ferumoxytol and was to be available as a solution for infusion (drip) into a vein.

How does Feraheme work?

The active substance in Feraheme, ferumoxytol, is an iron-containing compound. When injected into the blood, it is taken up by cells in the liver, spleen and bone marrow, where the iron is released from the compound and replenishes the body's low iron stores. With the increased iron stores, the body can produce more haemoglobin, which will help correct the anaemia.

What did the company present to support its application?

The company presented the results of three main studies conducted in patients with iron deficiency anaemia due to chronic kidney disease and two main studies conducted in patients with iron deficiency anaemia due to other causes who could not take iron supplements by mouth or for whom iron supplements did not work. The main measure of effectiveness was the change in the blood level of haemoglobin in patients given Feraheme compared with that in patients given other iron preparations

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

or placebo (a dummy treatment). The company also submitted supportive data on effectiveness and data on the safety of Feraheme from other studies.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

As results of the main studies showed that Feraheme was effective at treating iron deficiency anaemia due to different causes, the Agency considered that the proposed use of the medicine should cover all patients with iron deficiency anaemia, without differentiating between anaemia due to kidney disease and anaemia due to other causes.

In addition, the Agency raised a number of questions about uncertainties regarding the effectiveness and safety of Feraheme, to which the company would have needed to provide satisfactory answers before Feraheme could be authorised. At the time of the withdrawal, as the company had not yet responded to the questions, the Agency's opinion was that the benefits of Feraheme did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was doing so for business reasons.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Feraheme.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.