LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ferofix
(ferric hydroxide polymaltose complex)

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Summary Public Assessment Report

Ferofix
(ferric hydroxide polymaltose complex)

Chewable tablet, 100 mg

This is a summary of the public assessment report (PAR) for Ferofix. It explains how Ferofix was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Ferofix.

For practical information about using Ferofix, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ferofix and what is it used for?

Ferofix is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Ferofix is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Ferofix is used in the treatment of iron deficiency in adults and adolescents above the age of 12.

How does Ferofix work?

Ferofix contains the active substance iron, in the form of iron (III) hydroxide polymaltose complex.
Iron is an essential element required for the oxygen-carrying capacity of haemoglobine (the red pigment in the blood cells) and of myoglobin (the red pigment in muscle tissue). In iron deficiency the contents of the pigment are decreased and, if the iron deficiency persists, iron deficiency anemia (low level of hemoglobin and depletion of red blood cells) will occur.

How is Ferofix used?

The pharmaceutical form of Ferofix is chewable tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Ferofix have been shown in studies?

As ferric hydroxide polymaltose complex is a well-known substance, and its use in the treatment of iron deficiency in adults and adolescents above the age of 12 is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of ferric hydroxide polymaltose complex in the treatment of iron deficiency in adults and adolescents above the age of 12.

What are the possible side effects of Ferofix?

For the full list of all side effects reported with Ferofix, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Ferofix approved?

The use of Ferofix in the treatment of iron deficiency in adults and adolescents above the age of 12 is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Ferofix's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Ferofix is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ferofix, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Ferofix

The marketing authorisation for Ferofix was granted on 2017-11-06 in Sweden.

The full PAR for Ferofix can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Ferofix, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2017-11.