LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Diafer
(iron(III)isomaltoside 1000)

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Summary Public Assessment Report

Diafer
(iron (III) isomaltoside 1000)

solution for injection 50 mg/ml

This is a summary of the public assessment report (PAR) for Diafer. It explains how Diafer 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 Diafer.

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

What is Diafer and what is it used for?

Diafer is used for low levels of iron (called 'iron deficiency') if you have chronic kidney disease and are on dialysis provided oral iron cannot be used.

Diafer is used to replenish and maintain body iron stores by repeated treatment.

How does Diafer work?

Diafer contains a combination of iron and isomaltoside 1000 (a chain of sugar molecules). The type of iron in Diafer is the same as that found naturally in the body.

How is Diafer used?

The pharmaceutical form of Diafer is solution for injection.

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 Diafer have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Diafer is effective in treating low levels of iron if you have chronic kidney disease and are on dialysis provided oral iron cannot be used.

What are the possible side effects of Diafer?

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

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

Why is Diafer approved?

It was noted that Diafer was effective in treating low levels of iron if you have chronic kidney disease and are on dialysis provided oral iron cannot be used, based on literature data and clinical studies. Therefore, the Medical Products Agency in Sweden decided that Diafer'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 Diafer?

A risk management plan has been developed to ensure that Diafer 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 Diafer, 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 Diafer

The marketing authorisation for Diafer was granted on 2013-03-22 in Sweden.

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

This summary was last updated in 2015-01.