Version 4, 02/2016

PACKAGE LEAFLET

Package leaflet: Information for the user

Diafer® 50 mg/ml solution for injection

Iron

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Diafer is and what it is used for

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

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.

2. What you need to know before you receive Diafer

You must not receive Diafer
- if you have anaemia that is not caused by low levels of iron (deficiency), such as 'haemolytic' anaemia
- if you have too much iron (overload) or a problem in the way your body uses iron
- if you are allergic (hypersensitive) to the product or any of the other ingredients of the medicine (listed in section 6)
- if you have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations
- if you have active liver disease

Warnings and precautions
Talk to your doctor or nurse before receiving Diafer:
- if you have a history of medicine allergy
- if you have systemic lupus erythematosus
- if you have rheumatoid arthritis
- if you have severe asthma, eczema or other allergies

- if you have an ongoing bacterial infection in your blood

One ml of undiluted Diafer contains up to 4.6 mg (0.2 mmol) of sodium. This has to be taken into account in patients on a sodium-controlled diet.

Children and adolescents
Diafer is not tested in children and adolescents. For that reason children and adolescents should not have Diafer.

Other medicines and Diafer
Diafer given together with oral iron preparations can reduce the absorption of oral iron. Tell your doctor if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Diafer can affect the way some medicines work. Also some other medicines can affect the way Diafer works.

Pregnancy, breast-feeding and fertility
Diafer has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby. If you become pregnant during treatment, you must ask your doctor for advice. Your doctor will decide whether or not you should be given this medicine.

If you are breast-feeding, ask your doctor for advice before you are given Diafer.

Driving and using machines
Diafer is unlikely to impair the ability to drive or operate machines.

3. How Diafer is given

Your doctor or nurse will administer Diafer by injection into your vein or into the dialyser; Diafer will be administered in a structure where immunoallergic events can receive appropriate and prompt treatment.

You will be observed for at least 30 minutes by your doctor or nurse after each administration.

If you get more Diafer than you should
A qualified person will give you Diafer. It is unlikely that you will have too much. They will monitor your dose and blood to avoid iron building up in your body.

4. Possible side effects

Like all medicines Diafer can cause side effects, although not everybody gets them.

Allergic reactions

Tell your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath, and chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Very common (affects more than 1 user in 10):
- none

Common (affects less than 1 user in 10 and more than 1 in 100):
- none

Uncommon (affects 1 to 10 users in 1,000):

- blurred vision
- numbness
- hoarseness
- nausea, vomiting, constipation, pain in and around the stomach
- cramps
- hypersensitivity reactions (flushing, itchiness, rash, shortness of breath)
- feeling hot (or fever)
- soreness and swelling near the injection site

Rare (affects 1 to 10 users in 10,000):

- disturbances in heart rhythm
- chest pain
- loss of consciousness
- seizure
- dizziness, restlessness, fatigue
- diarrhoea, sweating, tremor
- angioedema (serious allergic reaction which causes swelling of the face and throat)
- pain in your muscles and joints
- low blood pressure
- altered mental status

Very rare (affects less than 1 user in 10,000):

- slow heart rate in foetus
- palpitations
- affection of red blood cells (this would show up in some blood tests)
- headache
- unusual feeling on the surface of your body
- temporary deafness
- raised blood pressure
- acute severe allergic reactions

Not known (cannot be estimated with the available data):

- Flu-like illness may occur a few hours to several days after injection and is typically characterised by symptoms such as high temperature, and aches and pains in muscles and joints.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diafer

Keep Diafer out of the sight and reach of children.

Do not freeze. Hospital staff will make sure that the product is stored and disposed of correctly. Do not use this medicine after the expiry date which is stated on the ampoule and the carton. EXP is the abbreviation used for expiry date. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Diafer contains

The active substance in Diafer is ferric derisomaltose. One millilitre of solution contains 50 mg iron as ferric derisomaltose. A 2 ml ampoule contains 100 mg iron as ferric derisomaltose.
The other ingredients are water for injections, sodium chloride, sodium hydroxide (pH adjuster) and hydrochloric acid (pH adjuster).

What Diafer looks like and contents of the pack

Diafer is a dark brown solution for injection contained in glass ampoule.
The pack sizes are the following:
Ampoule pack sizes: 1 x 2 ml, 5 x 2 ml, 10 x 2 ml, 25 x 2 ml

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Diafer
Belgium:	Diafer
Czech Republic:	Diafer
Denmark:	Diafer
Finland:	Diafer
Ireland:	Diafer
The Netherlands:	Diafer
Norway:	Diafer
Poland:	Diafer
Romania:	Diafer
Sweden:	Diafer
United Kingdom:	Diafer

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Other sources of information

The following information is intended for medical or healthcare professionals only:

Posology
Diafer may be administered as an up to 200 mg dosage with a maximum weekly administration of 1000 mg. If higher doses than 200 mg of iron are needed, other iron medicinal products intended for intravenous use should be used.

The iron dose must be individualised based on the clinical response to treatment including evaluation of haemoglobin, ferritin and tranferrin saturation, concommittant treatment with an erythropoiesis

stimulating agent (ESA) and the dosis of ESA treatment. Targets may vary from patient to patient and depending on local guidelines.

Maintenance therapy with iv iron treatment may be given as small doses administered at regular intervals to maintain iron status tests stable within specific limits with the intent of avoiding development of iron deficiency or decline of iron test parameters below specific levels.

Paediatric population:

Diafer is not recommended for use in children and adolescents < 18 years due to insufficient data on safety and efficacy in children.

Method of administration:

Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of Diafer.

Diafer should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Diafer injection.

Adults and the elderly:

Diafer can be administered either as an intravenous bolus injection or during a haemodialysis session directly into the venous limb of the dialyser. It may be administered undiluted or diluted in up to 20 ml sterile 0.9% sodium chloride.

Diafer should not be administered concomitantly with oral iron preparations, since the absorption of oral iron might be decreased.

Shelf life after dilution with sterile 0.9% sodium chloride

Chemical and physical in-use stability has been demonstrated for 48 hours at 30°C in dilutions with up to 20 ml sterile 0.9% sodium chloride.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of user.

Special precautions for disposal and other handling

Inspect ampoules visually for sediment and damage before use. Use only those containing sediment-free, homogeneous solution.

Diafer is for single use only and any unused solution or waste material should be disposed of in accordance with local requirements.

Diafer must only be mixed with sterile 0.9% sodium chloride. No other intravenous dilution solutions should be used. No other therapeutic agents should be added.

The diluted solution for injection should be visually inspected prior to use. Use only clear solutions without sediment.