

Treating iron deficiency with ferric derisomaltose Pharmacosmos 100 mg/ml solution for injection/infusion

Patient information

Why am I being treated with FDI?

FDI (which is short for ferric derisomaltose) is used for treating iron deficiency. Your doctor will have chosen this treatment because you need to correct the iron levels in your body.

Why do I need iron?

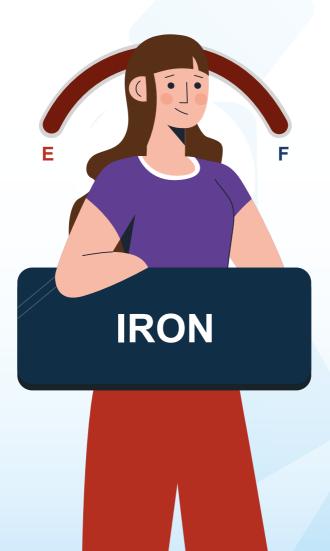
Iron plays a key role in many processes, especially in facilitating the formation of red blood cells and enabling them to carry oxygen around the body. A lack of iron can make us feel tired, dizzy, irritable, unable to sleep and lead to dry skin or hair loss.

Before receiving treatment

Treatment with FDI does not require any preparation from your side. Have your usual meals on the day and make sure you are well-hydrated. Continue taking all your usual medications, but stop any iron tablets at least a day before your appointment. Wear loose, comfortable clothes and a short-sleeved shirt. You can also bring along a book, or something to watch. We advise you to go through your full medical history with your doctor. Please note that this leaflet does not replace the Patient Information Leaflet, which your doctor or nurse can provide you with.

What is FDI?

FDI is a dark brown liquid containing iron. It is used for treating iron deficiency when oral iron preparations are ineffective or cannot be used, or when there is a need to deliver iron rapidly.



Administration

FDI is an intravenous iron treatment that is administered directly into a vein. This means the iron is delivered into your bloodstream via a drip, or you might receive it from a slow injection, all while being monitored by a nurse. The iron doesn't hurt, but you may feel a cold sensation in your arm.

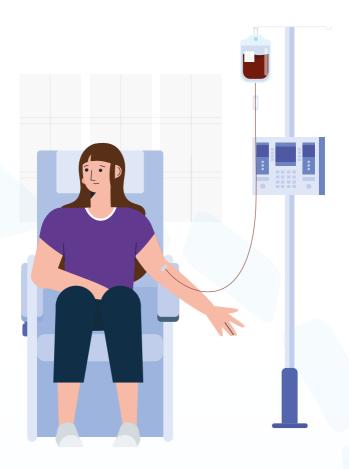
Are there any side effects during treatment?

Like all medicines, FDI can cause side effects, although not everybody gets them. Your doctor will discuss all possible side effects with you before starting treatment. For all intravenous iron treatments administered directly into your arm, there is a low risk that you may experience an acute severe hypersensitivity reaction. Symptoms can include breathing difficulty, dizziness and swelling in the mouth. Your doctor or nurse will be monitoring you closely to make sure your body is responding well to the treatment. There is a risk (uncommon) that iron could leak and cause a stain to your skin which may be permanent. If you experience pain, discomfort, or notice leaking around the treatment site, please let your doctor or nurse know immediately.

A few days after treatment, you might experience headache, mild fever or joint pain – these symptoms usually settle on their own. Tell your doctor or nurse if you experience any symptoms during treatment. The procedure will be stopped immediately – they'll take care of you, and let you know if it's possible to restart. You can find more information on possible side effects in the Patient Information Leaflet provided with your medicine.

How long will the infusion take?

It will take around 30 minutes to receive your iron. Your nurse or doctor will keep you for an additional 30 minutes afterwards to ensure you're well before going home.



What happens after treatment?

A new blood sample will usually be taken some weeks or months after the treatment to determine if your body's iron stores are fully corrected. Depending on your weight and how iron deficient you are, you may only need one treatment to restore your body's iron stores – unless you have ongoing issues that affect your iron levels.

Are you taking iron tablets?

If you are taking iron tablets on a daily basis, it is recommended that you discuss this with your doctor, as you will likely need to stop taking them for a while after your treatment with FDI.

Iron facts

- The human body contains 3–4 grams of iron, approximately two-thirds of this iron is found in the red blood cells
- Iron is needed to produce haemoglobin, the protein that transports oxygen around the body in red blood cells, and myoglobin, a similar protein that is found inside muscle tissue
- Iron is found in many enzymes, such as those that aid energy production. It is also used by the body for assisting the immune system
- Each day, an adult male requires around 11 milligrams (mg) of iron and an adult woman requires around 25 mg. This daily requirement usually comes from dietary sources

Sources: Stein J. et al. *Nat Rev Gastroenterol Hepatol*, 2010;7:599–610. WHO/FAO. Vitamin and mineral requirements in human nutrition. World Health Organization; 2004:1–341.

Reporting of side effects

Ferric derisomaltose

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine. FDI, ferric derisomaltose.

> If you need information or advice, please contact your nurse or doctor, who can also contact:

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UK-FDI-0423-00002 Date of preparation: April 2023