

MONOFER®

ferric derisomaltose

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Monofer.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Monofer against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What MONOFER is used for

Monofer contains a combination of iron and isomaltoside 1000 (a chain of sugar molecules). The type of iron in Monofer is the same as that found naturally in the body called 'ferritin'. This means that you can have Monofer by injection in high doses.

Monofer is used to correct for low levels of iron (sometimes called 'iron

deficiency' and 'iron deficiency anaemia') if:

- Oral iron does not work or you cannot tolerate it
- Your doctor decides you need iron very quickly to build up your iron stores.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Monofer is only available with a doctor's prescription. It is not addictive.

Before you are given MONOFER

When you must not be given it

You must not have Monofer if you have ever had an allergic reaction to ferric derisomaltose, the active ingredient in Monofer.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not have Monofer if:

- you have anaemia that is not associated with iron deficiency
- you have too much iron or a problem with the way your body uses iron

There is not enough information to recommend the use of Monofer in children.

Before you are given it

Tell your doctor if you have any of the following medical conditions:

- liver problems
- systemic lupus erythematosus (SLE) or a related disease
- rheumatoid arthritis
- severe asthma, eczema or other allergies
- ongoing bacterial infection in your blood.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Your doctor may want to take special precautions if you have any of these conditions.

Tell your doctor if you are pregnant or planning to become pregnant.

Ask your doctor about the risks and benefits involved in treatment with Monofer during pregnancy.

Tell your doctor if you are breast-feeding.

Monofer may slow the heart rate of your unborn baby for a short time if you have an allergic reaction to Monofer. Your doctor will carefully monitor your unborn baby if you need to be given Monofer while pregnant.

While it is unlikely to affect your baby, you should ask your doctor for advice before you are given Monofer.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Monofer given together with oral iron preparations can reduce the absorption of oral iron.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are receiving Monofer.

How MONOFER is given

How much you need

Your doctor will perform a blood test to determine the iron levels in your body. This will then help your doctor calculate the dose of Monofer you require.

How it is given

Monofer is usually given in a clinical setting equipped to provide intravenous infusions. The solution in the vial may be diluted with 0.9% sodium chloride. It can be given by slow injection directly from the syringe into a vein, or by infusion (drip) over a longer period, or during a haemodialysis session if you are receiving dialysis treatment.

How long your treatment will last

Your doctor will determine how long you will need to receive treatment with Monofer. You may receive a single infusion, or several infusions over several weeks.

If you have too much (overdose)

Too much Monofer may lead to accumulation of iron in your body. Your doctor will monitor the levels of iron in your body to make sure

that you do not receive too much Monofer.

While you are being given MONOFER

Things you must do

Before having any surgery or emergency treatment, tell the doctor that you are being treated with Monofer.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Monofer.

Tell any other doctor, dentist or pharmacist who treats you that you are being treated with Monofer.

Things to be careful of

Your doctor will need to be careful during treatment to avoid any leakage into your skin around the injection site. If a leak occurs the treatment must be stopped.

If there is any leak of Monofer at the injection site it may cause irritation of the skin or a brown discolouration at the injection site. Discolouration in other areas can also occur.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are receiving treatment with Monofer.

This medicine helps most people with iron deficiency, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or vomiting
- rash
- headache
- distorted sense of taste
- hoarseness or a sore throat
- pain in and around the stomach or stomach cramps
- indigestion, constipation or diarrhoea

Tell your doctor as soon as possible if you notice any of the following:

- blurred vision
- loss of consciousness
- dizziness or light headedness
- fatigue
- numbness
- tremor or seizure
- altered mental status
- fast or irregular heart beats
- low or high blood pressure
- chest pain
- flushing or sweating
- back pain, muscles or joint pain or muscle spasm
- fever or feeling cold/shivering
- infection
- soreness and swelling near the injection site
- flu-like symptoms, generally feeling unwell

The above side effects could become serious. You may need urgent medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, difficulty swallowing, shortness of breath, wheezing or troubled breathing, chest pain.

The above list includes very serious side effects. You may need urgent

medical attention or hospitalisation.

These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (abnormal blood test results including low level of phosphate in the blood and/or high levels of liver enzymes) can only be found when your doctor does tests from time to time to check your progress.

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After being given Monofer

Storage

It is unlikely that you will have to store Monofer at home.

Monofer will be stored for you by your doctor or the hospital. It should be stored below 30°C.

Disposal

Any unused Monofer will be disposed of by your doctor or the hospital

Product description

What it looks like

Monofer is a dark brown, non-transparent solution that comes in a clear glass vial. It contains the active ingredient, ferric derisomaltose, as a sterile solution for injection, supplied in vials of 5mL in packs of 1 vial.

Ingredients

Each 1mL of Monofer contains 100 mg of iron as ferric derisomaltose

It also contains:

- water for injections
- sodium hydroxide (to adjust pH)
- hydrochloric acid (to adjust pH)