CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MONOFER 100 mg parenteral solution for injection/infusion

MONOFER 500 mg parenteral solution for injection/infusion

MONOFER 1 000 mg parenteral solution for injection/infusion

One ml of solution contains 100 mg iron as ferric derisomaltose

Contains sugar: Approximately 20 % *w/v* derisomaltose

Read all of this leaflet carefully before you are given MONOFER

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What MONOFER is and what it is used for

MONOFER contains a combination of iron and derisomaltose (a chain of sugar molecules).

MONOFER is used in the treatment of low levels of iron (sometimes called 'iron deficiency') when you cannot take iron treatment by mouth or if your body requires the iron very quickly.

2. What you need to know before you receive MONOFER

MONOFER is for adults only. Children should not be administered MONOFER.

MONOFER should not be administered to you:

- If you are allergic (hypersensitive) to ferric derisomaltose or any of the other ingredients of MONOFER *(*listed in section 6).
- If you have experienced serious allergic (hypersensitive) reactions to other injectable iron products.
- If you have anaemia that is **not** caused by low levels of iron (deficiency), such as haemolytic anaemia listed in point 6.
- If you have too much iron (overload) or a problem in the way your body uses iron (e.g. haemochromatosis, haemosiderosis).
- If you have an ongoing bacterial infection in your blood.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have known allergies to any other medicine.
- If you have an illness of your immune system, such as systemic lupus erythematosus (a serious disease of the skin), or rheumatoid arthritis.
- If you have severe asthma or you have a history of asthma or problems with allergies, eczema or inflammation.
- If you have reduced liver function.
- If you have an acute or chronic infection.

- Incorrect administration of MONOFER may cause leakage of the product at the injection site, which may lead to irritation of the skin and potentially long-lasting brown discolouration at the site of injection. The administration must be stopped immediately when this occurs.

Children and adolescents

MONOFER is for adults only. Children and adolescents younger than 18 years of age should not be administered MONOFER.

If you are not sure if any of the above applies to you, talk to your doctor or healthcare professional before being administered MONOFER.

Other medicines and MONOFER

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular tell your doctor, nurse or pharmacist if you are taking iron containing medicines that you take by mouth. You should not take iron by mouth until at least 5 days after the last injection of MONOFER.

Having blood tests done while you are receiving MONOFER*:*

MONOFER may affect the results of some blood tests to measure bilirubin and calcium. If you have to take a blood test, inform the doctor that you are being treated with MONOFER.

If you are not sure if the above applies to you, talk to your doctor, nurse or pharmacist before receiving MONOFER.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being administered MONOFER.

If you become pregnant during treatment, you must ask your doctor for advice.

Your doctor will decide whether or not you should be given MONOFER.

If you are breastfeeding, ask your doctor for advice before you are given MONOFER.

Driving and using machines

It is not always possible to predict to what extent MONOFER may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MONOFER affects them.

3. How to receive MONOFER

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself MONOFER**.** It will be given to you by a person who is qualified to do so.

Due to the risk of allergic reactions you must be under close observation when MONOFER is being administered. MONOFER will be administered in an environment where patients can receive appropriate and prompt treatment for allergic reactions to MONOFER.

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

You will be given MONOFER by injection or infusion into your vein.

The dose will depend on your blood iron (haemoglobin) level and your weight.

Your doctor will calculate the dose for you. It is usually given to you once a week.

Your doctor will tell you how long your treatment with MONOFER will last. If you have the impression that the effect of MONOFER is too strong or too weak, tell your doctor or pharmacist.

If you receive more MONOFER than you should

Since a health care provider will administer MONOFER, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive MONOFER

Since a health care provider will administer MONOFER it is unlikely that the dose will be missed.

4. Possible side effects

MONOFER can have side effects.

Not all side effects reported for MONOFER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving MONOFER, please consult your health care provider for advice.

If any of the following happens, the administration of MONOFER should be stopped immediately and you should tell your doctor or the healthcare professional administering MONOFER:

- shortness of breath,
- swelling of hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- nettle rash or hives, flushing, rashes, itching,
- nausea and shivering,
- acute chest and/or back pain.

These are all very serious side effects. If you have them, you may have had a serious reaction to MONOFER. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- uneven (irregular) heartbeat, high pulse rate,
- chest pain,
- loss of consciousness,
- seizure (fits),
- altered mental status,

- in pregnancy, the baby's heart rate may slow,
- palpitations (pounding or racing heart),
- lower red blood cells than usual (this would show up in some blood tests,

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common

- nausea,
- rash,
- skin reactions at or near the injection site including redness of the skin, swelling, burning, pain, bruising, brown discolouration, leakage to the tissue around the site of infusion, irritation.

Uncommon

- hypersensitivity reactions with potential shortness of breath and bronchospasm,
- numbness,
- distortion of the sense of taste,
- blurred vision,
- loss of consciousness,
- wheezing,
- pain in and around the stomach (abdominal pain), being sick (vomiting), constipation, diarrhoea, impaired digestion,
- flushing, sweating, fever, feeling cold, shivering,
- dizziness,
- fatigue,
- increased heart rate,
- Chest pain, back pain, pain in your muscles or joints, muscle spasms,
- low or high blood pressure,

- Itching, hives, skin inflammation,
- flushing, sweating, fever, feeling cold, shivering,
- headache,
- unusual feeling on the surface of your body (pins and needles),
- low level of phosphate in the blood,
- infection,
- increased liver enzymes,
- local inflammation of a vein,
- skin exfoliation,
- general feeling of discomfort (malaise),
- tremor,
- hoarseness,
- seizure,
- altered mental status,

Rare

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 the muscles and joints.

Not known

- Skin discoloration at other areas of the body than the injection site.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8.

Acino Pharma (Pty) Ltd: E-mail: drugsafety_ZA@acino.swiss Tel: 060 998 7896.

By reporting side effects, you can help provide more information on the safety of MONOFER.

5. How to store MONOFER

Store all medicines out of reach of children.

- Store in a cool dark place at or below 30 °C.
- Store in the outer carton until required for use.
- Do not use after the expiry date stated on the ampoule or vial or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MONOFER contains:

Active ingredient: Iron as ferric derisomaltose.

Each 1 ml vial/ampoule contains 100 mg iron as

ferric derisomaltose.

Each 5 ml vial/ampoule contains 500 mg iron as derisomaltose.

Each 10 ml vial/ampoule contains 1 000 mg iron as ferric derisomaltose.

Inactive ingredients: Water for injection.

Contains no preservatives.

What Monofer looks like and contents of the pack

Solution for injection/infusion.

MONOFER 100 mg is a dark brown solution with no signs of precipitation filled into a 1 ml clear glass vial sealed with chlorobutyl rubber stopper and aluminium cap with white flip-off button or clear 1 ml glass ampoule with a break point. 5 vials or ampoules packed into an outer carton.

MONOFER 500 mg is a dark brown solution with no signs of precipitation filled into a 5 ml clear glass vial sealed with chlorobutyl rubber stopper and aluminium cap with white flip-off button or clear 5 ml glass ampoule with a break point. 5 vials or ampoules packed into an outer carton.

MONOFER1 000 mg is a dark brown solution with no signs of precipitation filled into a 10 ml clear glass vial sealed with chlorobutyl rubber stopper and aluminium cap with white flip-off button or clear 10 ml glass ampoule with a break point. 2 vials or ampoules packed into an outer carton**.**

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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Registration numbers

MONOFER100 mg: 46/8.3/0166

MONOFER 500 mg: 46/8.3/0167

MONOFER 1000 mg: 46/8.3/0168

Access to the corresponding Professional Information

The corresponding professional information can be found in the packaging of MONOFER.