

## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

**S3**

### **COSMOFER 50 mg solution for injection/infusion**

#### **Iron (III)–hydroxide dextran complex**

**Contains sugar: Approximately 20 % w/v low molecular weight dextran**

### **Read all of this leaflet carefully before you are given COSMOFER**

- 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 COSMOFER is and what it is used for
2. What you need to know before you receive COSMOFER
3. How to receive COSMOFER
4. Possible side effects
5. How to store COSMOFER
6. Contents of the pack and other information

#### **1. What COSMOFER is and what it is used for**

COSMOFER contains a combination of iron and dextran (a long chain of sugar molecules).

- iron deficiency (anaemia),
- if you cannot take iron by mouth.

#### **2. What you need to know before you receive COSMOFER**

**COSMOFER should not be administered to you:**

- If you are allergic (hypersensitive) to Iron (III)–hydroxide dextran complex or any of the other ingredients COSMOFER (listed in section 6).
- if you have experienced allergic (hypersensitive) reactions to other injectable iron.
- If you have allergies such as eczema, asthma or any other allergies.
- If you have anaemia that is not caused by low levels of iron (deficiency), ~~such as~~ e.g. haemolytic anaemia.
- If you have too much iron (overload) or a problem in the way your body uses iron.
- If you have liver problems such as cirrhosis or hepatitis.
- If you have a chronic bacterial or viral infection. because it can make the infection worse.
- If you suffer from rheumatoid arthritis and you have symptoms at the moment (active inflammation).
- If you have kidney problems, such as acute kidney failure.

**Warnings and precautions**

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

- If you have a history of medicine allergy, including severe hypersensitivity to other injectable iron preparations.
- If you have an illness of your immune system, such as systemic lupus erythematosus (a serious disease of the skin). Or rheumatoid arthritis. This is because you may be more likely to have an allergic reaction with **COSMOFER**.
- If you have asthma, eczema or problems with allergies or inflammation.

**Having blood tests while you are having COSMOFER:**

COSMOFER may affect the results of some blood tests that measure 'bilirubin' and calcium.

If you have to take a blood test, inform the doctor that you were given COSMOFER.

## **Children**

COSMOFER is for adults only. Children under 14 years should not receive **COSMOFER**.

## **Other medicines and COSMOFER**

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, or pharmacist if you are taking any of the following medicines:

- vitamins or minerals
- iron containing medicines you take by mouth. You should not take iron by mouth until at least 5 days after finishing COSMOFER.

## **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 receiving **COSMOFER**.

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

It is not known whether the active ingredient of **COSMOFER** is excreted into human breast milk. Therefore, you should not use **COSMOFER** during breastfeeding.

## **Driving and using machines**

It is not always possible to predict to what extent COSMOFER 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 COSMOFER affects them.

## **3. How to receive COSMOFER**

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

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

You will be given COSMOFER by injection or infusion into your vein or you may have it injected into a muscle, the COSMOFER will be administered in a facility where immuneallergic events can receive appropriate and prompt treatment, such as a hospital.

You will be observed for at least 60 minutes by your doctor or nurse after each administration. The dose depends on your blood iron (haemoglobin) level and your weight. Your doctor will calculate the dose for you. It is usually given to you two or three times each week.

**If you have never had COSMOFER before**

- Your doctor will monitor you closely during and immediately after you have had **COSMOFER**.
- If no reaction happens after 60 minutes, you will have the rest of the dose.

**If you have had COSMOFER before**

- The dose depends on your blood iron (haemoglobin) level and your weight.
- Your doctor will calculate the dose for you.
- It is usually given to you two or three times each week.

**If you are given more COSMOFER than you should**

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

They will monitor your dose so that an iron build-up does not happen in your body.

If you think you have been given too much, tell your doctor or nurse straight away.

**If you forget to receive COSMOFER**

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

**4. Possible side effects**

COSMOFER can cause side effects.

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

**If any of the following happens, COSMOFER should be stopped and you should tell your doctor immediately**

More serious allergic reactions may happen in the first few minutes of receiving COSMOFER (affecting less than 1 in 10 000 people) The signs may include:

- sudden onset of difficulty breathing (respiratory difficulty),
- serious problems with your heart and circulation (cardiovascular collapse),
- fatalities have been reported.

These may also occur up to one hour after receiving COSMOFER.

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

**Tell your doctor *if you notice any of the following:***

#### **Allergic reactions**

If you have an allergic reaction to **COSMOFER**, tell your doctor or nurse straight away so that they can stop it if necessary. The signs of this may include:

- shortness of breath,
- nettle rash or hives, flushing, rashes, itching,
- nausea and shivering,

Also there have been reports of delayed allergic reactions, that may happen a few hours or up to four days after being given COSMOFER. The signs may include:

- pain in your joints or muscles,
- sometimes a high temperature (fever).

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

**Tell your doctor if you notice any of the following:**

Uncommon:

- pain in and around the stomach (abdominal pain), being sick (vomiting),
- blurred vision,
- feeling hot,
- cramps,
- numbness.

Rare:

- loss of consciousness,
- altered mental status,
- seizures (fits),
- dizziness, restlessness, fatigue,
- low blood pressure,
- angioedema a type of severe allergic reaction, signs may include swelling,
- uneven (irregular) heartbeat, high pulse rate, chest pain,
- diarrhoea, sweating and tremor.

Very rare:

- lower red blood cells than usual (this would show up in some blood tests),
- headache,

- unusual feeling on the surface of your body,
- raised blood pressure,
- temporary deafness,
- palpitations,
- in pregnancy, the baby's heart rate may slow.
- Some other side effects have been reported. People with rheumatoid arthritis may have worsening of joint pain.

#### Not Known

- 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.

#### **Possible side effects after an injection into your vein**

If you have **COSMOFER** into a vein, there may be reactions, such as soreness and swelling (inflammation) around the vein. There have also been reports of inflammation of the vein.

#### **Possible side effects after an injection into your muscle**

If you have **COSMOFER** into a muscle, there may be reactions, such as staining of the skin, bleeding, formation of boils, tissue damage (necrosis or atrophy) and pain.

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 or 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](mailto:drugsafety_ZA@acino.swiss) Tel: 060 998 7896.

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

## 5. How to store COSMOFER

Store all medicines out of reach of children.

It is unlikely that you will be asked to store **COSMOFER** yourself. However, if you have to please:

- Store in a cool dark place at or below 25 °C.
- Store in the carton until required for use.
- Inspect ampoules visually for sediment and damage before use. Use only those containing sediment-free homogeneous solution.
- Do not freeze.
- Do not use after the expiry date stated on the ampoule 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 COSMOFER contains:

- The active substance is Iron (III)–hydroxide dextran complex equivalent to Iron (III).
- The other ingredients are hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.
- Contains no preservatives.

### What COSMOFER looks like and contents of the pack

COSMOFER is a dark brown solution filled into a 2 ml or 10 ml Type I clear glass ampoule with break point.

An outer carton box contains 2, 5 or 10 ampoules.

Not all pack sizes may be marketed.



**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**

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