

Package Leaflet: Information for the User

CosmoFer®, 50 mg/ml **solution for injection and for infusion** **Iron(III)**

Read all of this leaflet carefully

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet

1. What CosmoFer is and what it is used for
2. Before you are given CosmoFer
3. How CosmoFer is given
4. Possible side effects
5. How CosmoFer will be stored
6. Further 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). The type of iron in CosmoFer is the same as that found naturally in the body called 'ferritin'. This means that you can have CosmoFer by injection in high doses.

CosmoFer is used for low levels of iron (sometimes called 'iron deficiency') if:

- you cannot take iron by mouth, for example you cannot tolerate it
- you have taken iron by mouth and it has not worked
- your doctor decides you need iron very quickly to build up your iron stores.

2. Before you are given CosmoFer®

CosmoFer is for adults only. Children should not have this medicine.

You should not be given CosmoFer if:

- you have anaemia that is not caused by low levels of iron (deficiency), such as 'haemolytic' anaemia
- you have too much iron (overload) or a problem in the way your body uses iron
- you are having this medicine injected into a vein (intravenous injection) and you have a history of asthma, eczema or any other allergies. Your doctor or nurse may give the injection into your muscle in this case
- you have a history of allergy to any other drugs
- you have liver problems such as 'cirrhosis' or 'hepatitis'
- you have a bacterial or viral infection, because CosmoFer can make the infection worse
- you suffer from 'rheumatoid' arthritis and you have symptoms at the moment (active inflammation)
- you have kidney problems, such as acute kidney failure.

Do not have CosmoFer if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before having CosmoFer.

Take special care with CosmoFer

Using CosmoFer carries a risk of immediate severe and potentially fatal allergic reactions (see Section 4). Check with your doctor, nurse or pharmacist before having CosmoFer 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
- you have asthma or problems with allergies or inflammation.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having CosmoFer.

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because CosmoFer can affect the way some medicines work. Also some other medicines can affect the way CosmoFer works.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

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

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having CosmoFer.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

CosmoFer should not be used during the first three months of pregnancy. Your doctor will decide if the possible risks outweigh the expected benefit of treatment with CosmoFer during the last six months of pregnancy. He or she will then decide if you should be treated with CosmoFer, if it is clearly necessary.

It is not known whether the active ingredients of CosmoFer are excreted into human breast milk. Therefore, you should not use CosmoFer during breast-feeding unless your doctor decides that it is clearly necessary.

Driving and using machines

Ask your doctor if you can drive or operate machines after having CosmoFer.

Having blood tests while you are having CosmoFer

CosmoFer may affect the results of some blood tests to measure 'bilirubin' and calcium. Tell your doctor if you have any blood test while you are having CosmoFer.

3. How CosmoFer® is given

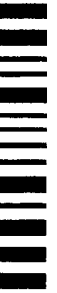
A trained and qualified person will give you CosmoFer under the supervision of a doctor.

How you will be given CosmoFer

You will have CosmoFer by injection or infusion into your vein, or you may have it injected into a muscle.

If you have never had CosmoFer before

- You will have a small amount of the medicine first (a test dose). This is to check that you are not allergic to it



- 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 get more CosmoFer than you should

A trained and qualified person will give you CosmoFer. It is unlikely that you will have too much. 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.

4. Possible side-effects

Like all medicines CosmoFer can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (affecting less than 1 in 100 people)

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.

More serious allergic reactions, may happen in the first few minutes of having 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.

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).

Please contact your doctor if you have any of these signs.

Other side effects include

Uncommon (affecting less than 1 in 100 people):

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

Rare (affecting less than 1 in 1,000 people):

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

Very rare (affecting less than 1 in 10,000 people):

- 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.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How CosmoFer® will be stored

This medicinal product does not require any special storage conditions. Hospital staff will make sure that the product is stored and disposed of correctly. CosmoFer should not be used after the expiry date which is stated on the ampoule. Exp. is the abbreviation used for expiry date. The expiry date refers to the last day of that month.

Keep out of the reach and sight of children.

6. Further information

What CosmoFer contains

- The active substance in CosmoFer is an Iron(III)-hydroxide dextran complex. A 2 ml ampoule contains 100 mg iron(III), a 5 ml ampoule contains 250 mg iron(III) and a 10 ml ampoule contains 500 mg iron(III)
- The other ingredients are Water for injections, Sodium hydroxide (pH adjuster) and Hydrochloric acid (pH adjuster).

What CosmoFer looks like and contents of the pack

CosmoFer is contained in clear glass ampoules. The pack sizes are the following: Packing containing 5 x 2 ml, packing containing 10 x 2 ml, packing containing 10 x 5 ml, packing containing 2 x 10 ml and packing containing 5 x 10 ml.

Marketing Authorisation Holder and Manufacturer

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark

Distributor UK and Ireland

Vitaline Pharmaceuticals UK Ltd.
Chiltern House
Unit P, Howland Road, Thame
Oxfordshire, OX9 3GQ
United Kingdom

This leaflet was last approved 03/2008

405188-11 10/08