

SCHEDULING STATUS: **S3****EQUIFER, 100 mg iron/5 ml solution for infusion****Iron (as iron (III)-hydroxide sucrose complex)****Contains sugar (sucrose 27-33 % w/v)****Please read all of this leaflet carefully before you are given EQUIFER**

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

What is in this leaflet

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

1. What EQUIFER is and what is used for

EQUIFER contains a combination of iron and sucrose (a long chain of sugar molecules).

EQUIFER is used for low levels of iron (sometimes called 'iron deficiency' or anaemia) if you cannot take iron by mouth.

2. What you need to know before you are given EQUIFER

EQUIFER is for adults only and should not be administered to children.

You should not be given EQUIFER if:

- You have a history of allergy to any other iron medicines, or you are allergic to EQUIFER or any of

its ingredients.

- You have low levels of red blood cells (anaemia), such as haemolytic anaemia, which is not caused by a shortage of iron.
- You have too much iron (overload) or a problem in the way your body uses iron.
- You have a history of asthma, eczema or any other allergies.
- You have liver problems such as hepatitis.
- You have an acute bacterial or viral infection, because it can make the infection worse.
- You are in the first three months of your pregnancy or breastfeeding your baby.

Do not take EQUIFER if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or healthcare professional before having EQUIFER.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection if:

- You are taking oral iron tablets or capsules.
- 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 EQUIFER can make the inflammation worse.
- You have low blood pressure.
- You are suffering from porphyria (a disorders of certain enzymes that normally participate in the production of porphyrins and heme).
- You have a vitamin D deficiency, are unable to absorb calcium and phosphates, have thyroid problems, a hereditary condition called hemorrhagic telangiectasia, inflammatory bowel disease, or osteoporosis. You may be more at risk of developing weak bones and fractures when receiving EQUIFER.

EQUIFER may cause your bones to weaken making you more prone to fractures. Tell your doctor if you experience worsening tiredness (fatigue) with muscle and bone pain during and after being treated with EQUIFER.

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

Children and adolescents

Do not give EQUIFER to children because it is unlikely to be safe.

Other medicines and EQUIFER

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

The use of EQUIFER with other medicines may cause undesirable interactions. Please always consult your doctor, pharmacist or other healthcare provider for advice.

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

- Iron containing medicines you take by mouth. You should not take iron by mouth until at least 5 days after finishing EQUIFER.
- An antibiotic called chloramphenicol.
- A medicine called enalapril used in the treatment of high blood pressure.

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

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 healthcare provider for advice before EQUIFER is administered to you.

EQUIFER should not be given to you during the first three months of pregnancy. Your doctor will decide on the benefit of treatment with EQUIFER during the last six months of pregnancy. He or she will then decide if you should be treated with EQUIFER, if it is clearly necessary.

It is not known whether the active ingredients of EQUIFER are excreted into breast milk. Therefore, you

should not use EQUIFER during breastfeeding unless your doctor decides that it is clearly necessary.

Driving and using machines

EQUIFER may make you feel dizzy, confused or lightheaded. If this happens, do not drive or use machines.

3. How EQUIFER is given

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

EQUIFER is not recommended for use in children.

You will not be expected to give yourself EQUIFER. A trained and qualified person (healthcare professional) will give you EQUIFER under the supervision of a doctor.

EQUIFER will be administered by injection or infusion into your vein.

If you have never had EQUIFER before

- You will have a small amount of EQUIFER 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 EQUIFER.
- If no reaction happens after 15 minutes, you will have the rest of the dose.

If you have had EQUIFER before

- The dose depends on your blood iron (haemoglobin) level and your weight.
- Your doctor will calculate the dose for you, depending on your individual needs and body weight.
- It is usually given to you not more than three times each week.

If you get more EQUIFER than you should

A trained and qualified person will give you EQUIFER. It is highly unlikely that you will be given too much. They will monitor your dose so that an iron build up does not happen in your body. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

EQUIFER can have side effects. Not all side effects reported for EQUIFER are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving EQUIFER, please consult your healthcare provider for advice.

If any of the following happens, the administration of EQUIFER must be stopped immediately as you are experiencing an allergic reaction to EQUIFER. The signs of an allergic reaction may include:

- shortness of breath, wheezing and cough
- throat, lips and tongue swelling
- nettle rash or hives, flushing, rashes, itching
- nausea and shivering.

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

Tell your doctor if you notice any of the following:

Reported frequently:

- metallic taste or taste disturbances
- headache or dizziness
- brown discolouration of the skin.

Reported less frequently:

- nausea, vomiting, stomach pain and diarrhoea
- breathlessness
- a sensation of tickling, tingling, burning, pricking, or numbness of your skin
- lightheaded feeling and confusion
- low blood pressure
- swelling of the arms and legs

- muscle pain or cramps
- chest pain or tightness in the chest
- abnormal heart rate.

The frequency of occurrence for the following side effects are unknown:

- back pain, swelling of joints
- weakening of bones due to low phosphate levels in the blood
- high blood pressure
- heart attack
- blood in your urine.

If you have EQUIFER into a vein, there may be reactions, such as soreness and swelling (inflammation) in the region of the injection site. There have also been reports of inflammation of the vein.

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

5. How to store EQUIFER

It is unlikely that you will be asked to store EQUIFER yourself, however, if you have to please:

- Store all medicines out of reach of children.
- Store in a cool dark place at or below 25 °C.
- Do not freeze.
- Store in the carton until required for use.

- Ampoules should be visually inspected for damage before use and only those with sediment free solution may be used. Residual contents must be discarded, once the vial has been opened.
- 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 EQUIFER contains

- The active substance is iron as iron (III)-hydroxide sucrose complex. Each 5 ml contains 100 mg iron.
- The other ingredients are water for injection and sodium hydroxide.

Contains no preservatives.

The osmolarity of the solution is between 1150 - 1350 mOsmol/l.

What EQUIFER looks like and contents of the pack

Dark brown solution free of any sediment.

EQUIFER is filled into 5 ml clear glass ampoules in packs of 5 ampoules.

Holder of Certificate of Registration

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