Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name: TEVIFER 100, TEVIFER 500 & TEVIFER 1000** **Dosage form & strength:** Solution for injection Each ml contains 50 mg of iron as ferric carboxymaltose

APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S3

TEVIFER 100; TEVIFER 500 and TEVIFER 1 000,

50 mg/ml solution for injection/infusion

One ml of solution contains 50 mg of iron as ferric carboxymaltose.

Read all of this leaflet carefully before you are given TEVIFER:

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

WHAT IS IN THIS LEAFLET:

1. WHAT TEVIFER IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE TEVIFER

3. HOW TEVIFER IS GIVEN

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TEVIFER

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT TEVIFER IS AND WHAT IT IS USED FOR:

TEVIFER is a medicine that contains iron.

Medicines that contain iron are used when you do not have enough iron in your body. This is called iron deficiency.

TEVIFER is used for the treatment of patients with iron deficiency, when oral iron preparations are ineffective or cannot be used. The aim of the therapy is to replenish body iron stores and to remedy anaemia, a lack of red blood cells due to iron deficiency.

Before administration, your doctor will perform a blood test to calculate the dose of TEVIFER you require.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE TEVIFER:

TEVIFER should not be administered to you:

- If you are hypersensitive (allergic) to ferric carboxymaltose or any of the other ingredients of TEVIFER (listed in **section 6**);
- if you have anaemia not caused by iron deficiency;
- if you have iron overload (too much iron in your body) or disturbances in utilisation of iron;
- during the first three months of pregnancy.

Warnings and precautions:

Tell your doctor or healthcare provider before receiving TEVIFER:

- If you have a history of allergies, including medicine allergy;
- if you have severe asthma, eczema or other allergies;
- if you have an infection;
- if you have renal or liver disorders;
- if you have or have had low levels of phosphate in the blood.

Incorrect administration of TEVIFER may cause leakage of the product at the administration site, which may lead to irritation of the skin and potentially long-lasting brown discolouration

at the site of administration. The administration must be stopped immediately when this occurs.

Children and adolescents:

TEVIFER should not be given to children under 18 years.

Other medicines and TEVIFER:

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

If TEVIFER is given together with oral iron preparations, then these oral preparations could be less efficient.

Pregnancy, breastfeeding and fertility:

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 receiving TEVIFER.

Pregnancy:

You should not receive TEVIFER during the first three months of pregnancy (see **TEVIFER should not be administered to you** above).

Breastfeeding:

If you are breastfeeding, ask your doctor for advice before receiving TEVIFER.

Fertility:

There are no data on the effect of TEVIFER on human fertility.

Driving and using machines:

After receiving TEVIFER, you may feel dizzy, confused or lightheaded. TEVIFER may impair the ability to drive or operate machines.

It is not always possible to predict to what extent TEVIFER may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which TEVIFER affects you.

TEVIFER contains sodium:

TEVIFER contains 4,23 mg sodium per millilitre of undiluted solution.

This has to be taken into account if you are on a sodium-controlled diet.

3. HOW TEVIFER IS ADMINISTERED:

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

You will not be expected to give yourself TEVIFER. It will be given to you by a person who is qualified to do so. Your doctor or nurse will administer TEVIFER undiluted by injection, during dialysis, or diluted by infusion.

Your doctor will perform a blood test to determine the dose you need, and your doctor will take responsibility for calculating the appropriate dose and choosing the route, frequency and duration of your treatment.

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

Test dose:

Before receiving your TEVIFER dose, your doctor will administer a test dose consisting of a smaller volume into your vein. This is to ensure that you are not allergic to TEVIFER.

TEVIFER will be administered in a facility where immunoallergic events can receive appropriate and prompt treatment. You will be observed for at least 30 minutes by your doctor or nurse after each administration.

Use in children:

TEVIFER is not for use in children under 18 years old.

If you receive more TEVIFER than you should:

Since a healthcare professional will administer TEVIFER, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
Overdose can cause accumulation of iron in storage sites. Your doctor will monitor iron parameters such as serum ferritin and transferrin to avoid iron accumulation.

If you forget to receive TEVIFER:

Since a healthcare provider will administer TEVIFER, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

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

If any of the following happens, stop receiving TEVIFER tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVIFER. 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:

- developing worsening of tiredness, muscle or bone pain (pain in your arms or legs, joints or back). That may be a sign of a decrease in blood phosphorus which might cause your bones to become soft (osteomalacia). This condition may sometimes lead to bone fractures. Your doctor may also check the levels of phosphate in your blood, especially if you need a number of treatments with iron over time.
- rash (e.g., hives), itching, difficulty breathing, wheezing and/or swelling of the lips, tongue, throat or body, and chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- decrease in blood phosphorous
- headache, dizziness

- high blood pressure,
- nausea
- injection/infusion site reactions
- stomach pain, constipation, diarrhoea
- rash
- increase in a liver enzyme called alanine aminotransferase

Less frequent side effects:

- numbness, tingling or prickling sensation on the skin, a change in your taste sensation
- anxiety
- high heart rate
- low blood pressure, inflammation of a vein, fainting, feeling faint
- difficulty breathing, wheezing
- vomiting, indigestion, wind (flatulence)
- itching, hives, redness of the skin, rapid swelling of the face, mouth, tongue or throat which may cause difficulty in breathing, skin discolouration at other areas of the body than the administration site
- muscle-, joint -and/or back pain, pain in arms or legs, muscle spasms
- fever, tiredness, chest pain, chills, a general feeling of discomfort, flu-like symptoms
- increase in certain liver enzymes called aspartate aminotransferase, gamma-glutamyltransferase and alkaline phosphatase, and increase in an enzyme called lactate dehydrogenase
- feeling hot (flushing)

Side effects with unknown frequency:

- loss of consciousness

- swelling of the face

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TEVIFER.

5. HOW TO STORE TEVIFER:

Store all medicine out of reach of children.

Store at or below 25 °C.

Store in the original package until required for use.

TEVIFER will normally be stored for you by your doctor or the hospital.

Once the TEVIFER vials have been opened, they should be used immediately. After dilution with sodium chloride solution, the diluted solution should be used immediately.

Do not use the vials after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TEVIFER contains:

The active ingredient is ferric carboxymaltose.

The other ingredients are: sodium hydroxide and hydrochloric acid (for pH adjustment) and water for injection.

What TEVIFER looks like and contents of the pack:

TEVIFER is a dark brown, non-transparent, aqueous solution.

TEVIFER solution for injection/infusion 50 mg/ml, 2 ml, 10 ml and 20 ml are packed into colorless, Type I glass vials with bromobutyl rubber stopper and an aluminium cap.

– 2 ml solution containing 100 mg iron. Available in pack sizes of 1, 2 and 5 vials.

– 10 ml solution containing 500 mg iron. Available in pack sizes of 1, 2 and 5 vials.

– 20 ml solution containing 1000 mg iron. Available in a pack size of 1 vial.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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