PATIENT INFORMATION LEAFLET

1. **SCHEDULING STATUS**

Schedule 3

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

INNOFER (solution for Injection)

Iron in the form of Iron (III) – Hydroxide Sucrose.

INNOFER contains sugar

Read all of this leaflet carefully before are given INNOFER.

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

What is in this leaflet

- **WHAT INNOFER IS AND WHAT IT IS USED FOR:**

INNOFER 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”.

INNOFER will be administered to you if:

- You cannot take iron by mouth - such as when iron tablets make you feel ill.
- You have taken iron by mouth - and it has not worked**.**

WHAT YOU NEED TO KNOW BEFORE INNOFER IS ADMINISTERED TO YOU

INNOFER should not be administered to you

- If you are allergic to the iron or any of the components **INNOFER** (see **WHAT INNOFER CONTAINS**.
- You have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.
- If you have anaemia which is not caused by a shortage of iron
- If you have too much iron in your body or a problem in the way your body uses iron.
- If you have any infections
- If you have liver problems or infectious hepatitis (conditions that cause dark urine, yellow skin and eyes, loss of appetite, abdominal pain)
- If you have a history of asthma, eczema (a condition where patches of skin become inflamed, itchy, red), other allergic disorders (red eyes, itchy rash, runny nose)
- If you are in your first trimester of pregnancy or breastfeeding
- If you are a child

Tell your doctor or healthcare provider before being given the injection:

- If you have a history of medicine allergy
- If you have systemic lupus erythematosus
- If you have rheumatoid arthritis

- If you have a history of medicine allergies.
- If you have systemic lupus erythematosus (is an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs).
- If you have rheumatoid arthritis (is an autoimmune disease in which the body's immune system mistakenly attacks the joints of the body).
- If you have Porphyria Cutanea Tarda (PCT) (a form of porphyria that primarily affects the skin.
- If you have a vitamin D deficiency.
- If you have low levels of calcium and phosphate in your body.
- If you have a condition called secondary hyperparathyroidism or hereditary haemorrhagic telangiectasia.
- If you suffer from inflammatory bowel disease (IBS) or osteoporosis.

Other medicines and INNOFER:

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

In particular tell your doctor or healthcare professional if you are taking medicines that contain iron which you take by mouth.

You should not take oral iron tablets together with the **INNOFER** injection, and should not start oral iron tablets earlier than 5days after the **INNOFER** injection

INNOFER with food and drink and alcohol

INNOFER can be administered irrespective of whether food is taken or not.

Pregnancy and breastfeeding and fertility

- **INNOFER** Injection should not be administered to you during the first trimester of pregnancy. If you are pregnant or think you could be pregnant, or if you are

- planning to become pregnant, please inform your doctor. Consult your doctor if you are unsure or need advice.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice, before INNOFER is administered to you.

Driving and using machinery

You may feel dizzy, confused or lightheaded after being given **INNOFER**. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure.

INNOFER contains:

Contains sucrose (sugar). Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **INNOFER.**

INNOFER Injection contains the following inactive ingredients:

water for injections.

3. **HOW INNOFER WILL BE ADMINISTERED TO YOU:**

Always take **INNOFER** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide how much **INNOFER** to give you. He or she will also decide how often you need it and for how long. Your doctor will do a blood test to help work out the dose.

Your doctor or healthcare professional will administer **INNOFER** in one of the following ways:

- Slow injection or infusion (drip)into your vein – 1 to 3 times per week.
- If you undergo dialysis, **INNOFER** will be put into the venous line of the dialysis machine.

INNOFER will be administered in a structure where allergic events can receive appropriate and prompt treatment.

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

Use in children:

INNOFER is not recommended for use in children.

If more INNOFER than you should receive is administered to you:

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

4. POSSIBLE SIDE EFFECTS

INNOFER can have side effects.

If you have an allergic reaction, tell your doctor, pharmacist or healthcare professional straight away. The signs may include:

- Low blood pressure (feeling dizzy, light-headed or faint).

- Swelling of your face.
- Difficulty breathing.

Other frequently occurring side effects may include:

- Changes in your taste such as a metallic taste. This does not usually last very long.
- Low blood pressure or high blood pressure.
- Feeling sick (nausea).
- Pain around the site of injection.

Other less frequent side effect that may occur when **INNOFER** is administered:

- Headache or feeling dizzy.
- Stomach pain or diarrhoea.
- Being sick (vomiting).
- Wheezing, difficulty in breathing.
- Itching, rash, hives, skin redness;
- Muscle cramps or muscle pain.
- Reactions around the site of injection such as a feeling of burning, irritation or
- Discolouration or pain following the leakage of the injection into the skin.
- Abnormally high concentration of red blood cells in the blood.

- Burning sensation.
- Tingling or “pins and needles”.
- Reduced sensation of touch.
- Vein inflammation,
- Changes to the colour of your urine.
- Constipation.

- Joint pain.
- Extremity pain.
- Back pain.
- Chills, trembling or shaking
- Weakness, tiredness.
- Pain.
- Increased levels of liver enzymes (GGT, ALT, AST) in the blood.
- Abnormal liver function tests.
- Sleepiness or drowsiness.
- Pounding heart beat (palpitations).
- Flushing.
- Dry mouth.
- Discomfort in extremities.
- Muscle spasms.
- Chest pain.
- Fever.
- Itching or bruising at the injection site.
- Increased serum ferritin levels (possibly due to increased iron levels).

- Fainting.
- Feeling hot.
- Lung infection.
- Migraine headache.

Other side effects with unknown frequencies:

- Feeling less alert
- feeling confused;
- loss of consciousness;
- increased sweating
- itching, hives, rash or
- skin redness;
- Bone pains, muscle weakness, height loss (this is signs you are suffering from Hypophosphataemic Osteomalacia)

Not all side-effects reported for INNOFER are included in this leaflet. Should your general health worsen while taking INNOFER, please consult your doctor, pharmacist or other healthcare professional for advice.

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

5. STORING AND DISPOSING OF INNOFER

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.

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

Store at or below 30 °C in the original carton until removed for use. Protect from light. Do not freeze.

6. Contents of the pack and other information:

What INNOFER contains:

INNOFER is an injection that contains 100 mg iron in the form of Iron (III) – Hydroxide Sucrose Complex per 5 mL; 20 mg iron per ml.

INNOFER Injection contains the following inactive ingredients:

water for injections

INNOFER contains sucrose.

What INNOFER looks like and contents of the pack:

INNOFER is a homogenous brown liquid filled in 5 ml clear USP Type1 glass ampoules.

The solution for injection is filled into 5 ml clear ampoules, flat based constricted neck of colourless natural glass USP Type 1 with a purple colour snap off cap in packs of 5 ampoules in a tray packed in a carton.

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INNOFER.**

HOLDER OF CERTIFICATE OF REGISTRATION:

Innovata Pharmaceuticals Pty Ltd

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

26 May 2020

REGISTRATION NUMBERS

50/8.3/0580

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INNOFER.**

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below: