PATIENT INFORMATION LEAFLET FOR RAUTEVENE 100 mg/5 ml Solution for injection / Concentrate for solution for infusion

Scheduling status: **S3**

RAUTEVENE 100 mg/5 ml solution for injection / concentrate for solution for infusion

Iron

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- RAUTEVENE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects experienced become serious, please inform your doctor.

1. What RAUTEVENE contains:

The active substance is iron sucrose equivalent to 100 mg iron per 5 ml ampoule.

The other ingredient is water for injection.

Contains no preservatives.

Contains sugar (approximately 30 % sucrose).

2. What RAUTEVENE is used for:

RAUTEVENE is a medicine that contains iron.

Medicines that contain iron are used for “iron deficiency” i.e. when there is not enough iron in the body.

RAUTEVENE is given when:

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

3. Before you are given RAUTEVENE:

You should not be given RAUTEVENE:

- if you are hypersensitive (allergic) to iron or any of the ingredients of RAUTEVENE.
- if 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 a history of asthma, eczema or anaphylactic (shock) reactions or other allergies.
- if you are in the first trimester of pregnancy (i.e. first three months).
- if you have any infections.
- if you have liver problems.

Tell your doctor or healthcare professional before being given RAUTEVENE if any of the above applies to you.

Safety during breastfeeding has not been established.

Special care should be taken with RAUTEVENE:

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

- if you have a history of medicine allergy.
- if you have systemic lupus erythematosus (an immune system disease).
- if you have rheumatoid arthritis (a disorder that causes joint inflammation).
- if you have folic acid deficiency you may be at an increased risk of allergic or anaphylactic reactions.
- if you suffer from porphyria (a rare hereditary disease in which the blood pigment haemoglobin is abnormally metabolised) as safety has not been established.

Hypersensitivity (allergic) reactions may occur with RAUTEVENE. If you notice any signs or symptoms of an allergic reaction such as swelling of your face, hands, feet, mouth or throat, tongue and difficulty breathing, inform your doctor immediately.

Pregnancy and breastfeeding:

RAUTEVENE should not be given during the first three months of pregnancy.

Your doctor will decide if RAUTEVENE can be used during the fourth to ninth month of pregnancy.

RAUTEVENE should only be used in pregnant women where there is severe iron deficiency anaemia.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving RAUTEVENE.

Safety during breastfeeding has not been established.

Driving and using machinery:

You may feel dizzy, confused or lightheaded after being given RAUTEVENE.

If this happens do not drive or use any tools or machines.

Refer to your doctor, pharmacist or other healthcare professional if you are unsure.

Important information about some of the ingredients of RAUTEVENE:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before being given RAUTEVENE.

RAUTEVENE contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with RAUTEVENE:

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

It is very important to inform your doctor if you are taking medicines that contain iron which you take by mouth. These may not work if they are taken at the same time that RAUTEVENE is given to you.

4. How to receive RAUTEVENE:

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

RAUTEVENE can be given to you in three different ways:

- slow injection into your vein – 1 to 3 times per week.
- an infusion (drip) into your vein – 1 to 3 times per week.
- during dialysis – it will be put into the venous limb of the dialyser.

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

Your doctor will decide how much RAUTEVENE to give you.

He or she will also decide how often you need it and for how long.

Your doctor will carry out a blood test to help work out the dose.

If you have never had RAUTEVENE before, you will be given a small amount of the medicine first (a test dose). This is to ensure that you are not allergic to the medicine.

RAUTEVENE is a brown liquid and so the injection or infusion will look brown.

RAUTEVENE is not recommended for use in children.

If you are given more RAUTEVENE than you should have:

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

5. Possible side effects:

RAUTEVENE can have side effects.

Not all side effects reported for RAUTEVENE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving RAUTEVENE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately:

Allergic reactions:

Signs of an allergic reaction are infrequent and may include the following:

- low blood pressure (feeling dizzy, lightheaded or faint),
- swelling of your face, hands, feet, lips, mouth or throat or tongue,
- difficulty breathing,

- itching or rash.

Please inform your doctor or nurse straight away if you think you are having an allergic reaction. You may need urgent medical attention.

Other side effects include:

Frequent:

- changes in your taste (metallic taste). This usually does not last very long.

Less frequent:

- increased pulse rate
- headache or feeling dizzy
- low blood pressure and collapse
- pounding heart beat (palpitations)
- stomach pain or diarrhoea
- feeling sick (nausea) or being sick (vomiting)
- wheezing, difficulty in breathing
- itching, hives, rash or skin redness
- muscle cramps or muscle pain
- flushing
- fever or shivering
- chest pain and chest tightness
- reactions around the site of injection such as inflammation, a feeling of burning
- fainting
- loss of consciousness
- tingling or “pins and needles”
- a feeling of burning
- high blood pressure
- feeling hot

- swelling
- pain in your joints
- swelling of hands and feet
- tiredness, weakness or general feeling of illness
- feeling less alert, lightheaded or confused
- swelling of your joints, face and tongue
- increased sweating
- back pain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. Storing and disposing of RAUTEVENE:

Store at or below 25 °C, in the original carton, until required for use.

Do not refrigerate or freeze.

Solution for injection*:*

Once the ampoules have been opened they should be used immediately.

Concentrate for solution for infusion*:*

Once prepared (diluted), the solution for infusion should be used immediately.

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

Keep all medicines out of reach of children.

7. Presentation of RAUTEVENE:

5 ml clear glass ampoules in packs of 5 ampoules.

8. Identification of RAUTEVENE:

Dark brown solution in 5 ml clear glass ampoules.

9. Registration number:

46/8.3/0849

10. Name and business address of the holder of the certificate of registration:

Gen-Eye (Pty) Ltd[1]

Unit 7, Royal Palm Business Estate

646 Washington Street, Halfway House, Midrand, 1685

Gauteng, South Africa

11. Date of publication:

Date of registration: 05 December 2013

Date of the most recently revised patient information leaflet as approved by SAHPRA: 09 February 2022

[1] Company Registration number: 2009/009360/07

Namibia:
Scheduling status: NS2
Registration number: 15/8.3/0143

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