PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:

NOXFIBRA 20 (Solution for injection)

NOXFIBRA 40 (Solution for injection)

NOXFIBRA 60 (Solution for injection)

NOXFIBRA 80 (Solution for injection)

NOXFIBRA 100 (Solution for injection)

Read all of this leaflet carefully before you start using NOXFIBRA:

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

1. WHAT NOXFIBRA CONTAINS:

The active substance is enoxaparin.

Each pre-filled syringe contains:

Noxfibra 20: Enoxaparin sodium 20 mg/0,2 mℓ

Noxfibra 40: Enoxaparin sodium 40 mg/0,4 mℓ

Noxfibra 60: Enoxaparin sodium 60 mg/0,6 mℓ

Noxfibra 80: Enoxaparin sodium 80 mg/0,8 mℓ

Noxfibra 100: Enoxaparin sodium 100 mg/mℓ

The other ingredient is:

Water for injection.

2. WHAT NOXFIBRA IS USED FOR:

NOXFIBRA is one of a group of medicines called low molecular weight heparins (LMWH). NOXFIBRA works by reducing blood clotting.

NOXFIBRA is used to:

- Prevent blood clots from forming after an operation.
- Prevent blood clots from forming during hospitalisation or extended bed rest.
- Treat blood clots in veins.
- Treat certain types of heart disease (e.g. angina and heart attacks), when used with aspirin.
- Prevent blood clots from forming during purification of the blood by an artificial kidney (haemodialysis).

3. BEFORE YOU USE OR RECEIVE NOXFIBRA:

You should not use or receive NOXFIBRA if you have or ever had:

- An allergy to NOXFIBRA, heparin or its derivatives (see "WHAT NOXFIBRA CONTAINS"). Some signs and symptoms of an allergic reaction can include swelling of the face, lips or tongue, wheezing or troubled breathing, skin rash, itching hives, blisters of peeling skin.
- Active bleeding from any site.
- A major bleeding disorder or blood clotting problem (such as excessive bleeding), including certain cerebrovascular disorders or hereditary heparin-associated blood disorders.
- Stomach or bowel problems such as ulcers or ulcerative colitis.
- Bacterial infection of the heart.
- Severe or uncontrolled high blood pressure.

Do not give NOXFIBRA to a child, pregnant or lactating women or patients with prosthetic heart valves, as safety and efficacy has not been established.

Take special care with NOXFIBRA:

- You should not use NOXFIBRA interchangeably with any medicines with similar activity /effects as NOXFIBRA.
- NOXFIBRA must not be administered into the muscles.
- You should go for regular platelet tests when using NOXFIBRA.

It is very important to tell your doctor that you are using NOXFIBRA:

- If your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural anaesthesia).
- If you have a condition where the potassium in your blood is higher than normal.
- If you suffer from excessive bleeding caused by heparin.
- If you have to go for a procedure to ensure adequate blood flow to an organ or part of the body, especially the heart muscles.
- If you are pregnant or have a mechanical prosthetic heart valve, or both.
- If you have a severe liver disorder.
- If you have a kidney disorder.
- If you suffer from excessive bleeding.
- If you have or ever had a stomach ulcer.
- If you suffer from a condition where your body is unable to stop bleeding.
- If you recently had a stroke.
- If your blood pressure is not controlled.
- If you suffer from a condition called diabetes mellitus (high blood sugar) that is affecting your eyes.
- If you recently had eye- or nerve surgery.
- If you are using/taking other medicines that may affect blood clotting.
- If you are elderly, you may have in increased risk of bleeding.
- If your body weight is low (less than 45 kg for women and less than 57 kg for men).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult with your doctor, pharmacist or other healthcare professional for advice before being given this medicine.

Please inform your doctor if you have a prosthetic heart valve (see “Take special care with NOXFIBRA”).

Driving and using machinery:

Use caution when driving; performing dangerous activities or operating machinery until you know how NOXFIBRA affects you.

Taking other medicines with NOXFIBRA:

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

Tell your healthcare professional if you are taking:

- Any medicine used to stop bleeding.
- Medicines called NSAID (nonsteroidal anti-inflammatory medicines) used for pain and inflammation.
- Medicine called dextran, used to treat hypovolemia (decreased volume of circulating blood plasma).
- Medicine called ticlopidine which may be used in combination with aspirin following certain types of heart procedures (such as coronary stent implant).
- Medicine called clopidogrel, used to prevent heart attacks and strokes in persons with heart disease (recent heart attack), recent stroke, or blood circulation disease (peripheral vascular disease). It is also used with aspirin to treat new/worsening chest pain (new heart attack, unstable angina) and to keep blood vessels open.
- Medicine called systemic glucocorticoids, used to treat inflammation.
- Any medicine used to prevent or reduce the risk of blood clots.

4. HOW TO USE OR RECEIVE NOXFIBRA:

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

Your doctor will tell you how long your treatment with NOXFIBRA will last.

NOXFIBRA is usually administered under the skin or through the intravenous route. Intravenous administration will be done by a doctor or a nurse in a hospital. The recommended site for the injection is the stomach area. A different injection site will be used for each injection. You should not rub the injection site after administration.

NOXFIBRA may be given by your doctor, nurse or yourself.

You doctor will tell you how you will be given your injection.

Your doctor will determine the dose for your treatment.

Do not administer NOXFIBRA into the muscles.

If you take or receive more NOXFIRBA than you should:

In the event of overdosage, which may result in severe bleeding, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of NOXFIBRA:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

NOXFIBRA can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Bleeding (including nosebleeds, bleeding under the skin), bruising more easily than normal.
- Dark urine, fever, joint pain, loss of appetite, nausea and vomiting, weakness and fatigue, yellowing of your skin and the whites of your eyes.

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

Tell your doctor immediately or go to the nearest casualty department if you notice any of the following:

- Changes in the way your heart beat, muscle weakness or tiredness, which may be signs of hyperkalaemia, a condition where there is too much potassium in your blood.

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

Tell your doctor if you notice any of the following:

- Pain, bruising or irritation at the injection site after NOXFIBRA has been given.
- Hard inflamed nodules at the injection site.
- If you notice any dead skin at the injection site.
- Headaches.
- If you experience infections more often than usual.
- Thinning of your bones, with reduction in bone mass, which may be signs of osteoporosis.

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

6. STORING AND DISPOSING OF NOXFIBRA:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Do not freeze.

For single, one-time use only.

Any unused solution should be discarded.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF NOXFIBRA:

Noxfibra 20	:	is a 0,2 mℓ (20 mg/0,2 mℓ) solution for injection, packed in a 0,5 mℓ clear and colourless type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and an automatic safety device. The plunger rod is white in colour.
Noxfibra 40	:	is a 0,4 mℓ (40 mg/0,4 mℓ) solution for injection, packed in a 0,5 mℓ clear and colourless type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and an automatic safety device. The plunger rod is yellow in colour.
Noxfibra 60	:	is a 0,6 mℓ (60 mg/0,6 mℓ) solution for injection, packed in a 1 mℓ clear and colourless type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and an automatic safety device. The plunger rod is orange in colour.
Noxfibra 80	:	is a 0,8 mℓ (80 mg/0,8 mℓ) solution for injection, packed in a 1 mℓ clear and colourless type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and an automatic safety device. The plunger rod is brown in colour.

Noxfibra 100 : is a 1 mℓ (100 mg/mℓ) solution for injection, packed in a 1 mℓ clear and colourless type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and an automatic safety device. The plunger rod is black in colour.

The pre-filled syringes are packed into an outer cardboard carton.

NOXFIBRA pre-filled syringes are packed in 10's.

8. IDENTIFICATION OF NOXFIBRA:

Noxfibra is a clear, colourless solution (clear liquid) that is free from visible particulate matter.

9. REGISTRATION NUMBERS:

Noxfibra 20 : 52/8.2/0495

Noxfibra 40 : 52/8.2/0496

Noxfibra 60 : 52/8.2/0497

Noxfibra 80 : 52/8.2/0498

Noxfibra 100 : 52/8.2/0499

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

72 Steel Road

Spartan

Kempton Park, 1619

11. DATE OF PUBLICATION:

Date of registration: 25 February 2020

Date of most recent approval of professional information: 25 February 2020

[1]Company Reg. No.: 1990/001979/07