

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Enoxaparin sodium Impact 4 000 IU (40 mg)/0.4 ml Solution for Injection in Pre-Filled Syringe**

### **Enoxaparin sodium Impact 6 000 IU (60 mg)/0.6 ml Solution for Injection in Pre-Filled Syringe**

### **Enoxaparin sodium Impact 8 000 IU (80 mg)/0.8 ml Solution for Injection in Pre-Filled Syringe**

enoxaparin sodium

**sanofi**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

#### **1. WHAT ENOXAPARIN SODIUM IMPACT IS AND WHAT IT IS USED FOR**

Enoxaparin sodium Impact contains an active substance called enoxaparin sodium. It belongs to a class of medicines called "low molecular weight heparin" or LMWH.

#### **How Enoxaparin sodium Impact works**

Enoxaparin sodium Impact works in two ways:

- 1) By preventing existing blood clots from growing. This allows your body to break them down and prevent them from harming you.
- 2) By preventing the formation of new blood clots in your blood.

#### **What Enoxaparin sodium Impact is used for**

Enoxaparin sodium Impact can be used to:

- Treat blood clots in your blood
- Stop blood clots from forming in your blood in the following situations:

- before and after a surgical procedure
- if you have a short-term illness and you will not be able to move for a certain period of time
- Stop blood clots from forming when you have unstable angina (in which your heart receives an insufficient amount of blood) or after a myocardial infarction (heart attack)
- Stop blood clots from forming in the dialysis machine circuits (used for people with serious kidney disease).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE ENOXAPARIN SODIUM IMPACT**

### **Contraindications**

#### **Do not use Enoxaparin sodium Impact**

- if you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine product (listed in section 6)
  - heparin or other low-molecular-weight heparins, such as nadroparin, tinzaparin or dalteparin.

Signs of an allergic reaction include: skin rash, difficulty breathing or swallowing, swelling of the face, lips, tongue oral cavity, throat or eyes.

- you have had a reaction to heparin that has caused a significant decrease in the number of your coagulation cells (platelets) over the past 100 days
- you have antibodies to enoxaparin in your blood
- you have a lot of bleeding or you have a condition associated with a high risk of bleeding such as:
  - a stomach ulcer, recent surgery of the brain or eyes or a recent haemorrhagic stroke.
- you are using Enoxaparin sodium Impact to treat blood clots and must undergo the treatment within 24 hours:
  - spinal or lumbar puncture
  - surgical procedure with spinal or epidural anaesthesia.

Do not use Enoxaparin sodium Impact if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Enoxaparin sodium Impact.

### **Warnings and precautions**

Enoxaparin sodium Impact should not be replaced by other low-molecular-weight heparins such as nadroparin, tinzaparin or dalteparin. This is due to the fact that they are not exactly identical and do not have the same activity or the same instructions for use.

Talk to your doctor or pharmacist before using Enoxaparin sodium Impact if:

- you have ever had a reaction to heparin that caused a significant decrease in the number of coagulation cells (platelets)
- you have a heart valve
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of stomach ulcer
- you have recently had a stroke
- you have hypertension
- you have diabetes or problems with the blood vessels in your eye caused by diabetes (called diabetic retinopathy)
- you have recently had an eye or brain operation
- you are elderly (over 65 years of age) and in particular if you are over 75 years of age
- you have renal failure
- you have liver failure
- you are underweight or overweight
- you have a high level of potassium in your blood (this can be verified by a blood test)

- you are currently using medicines that increase the risk of bleeding (see section 2 - Other medicines and Enoxaparin sodium Impact)
- you have a problem with your spine or have had a surgical procedure on your spine.

If any of the above applies to you or if you are unsure, talk to your doctor or pharmacist before using Enoxaparin sodium Impact.

For patients receiving doses greater than 210 mg/day, this medicinal product contains more than 24 mg sodium (main component of cooking/table salt) per dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

### **Tests and controls**

You may need to have a blood test before you start using this medicine and regularly during use; this will check the level of platelets (clotting cells) and potassium in your blood.

### **Children and adolescents**

The safety and efficacy of Enoxaparin sodium Impact have not been evaluated in children or adolescents.

### **Other medicines and Enoxaparin sodium Impact**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- warfarin (used to thin the blood)
- aspirin (also called acetylsalicylic acid or ASA), clopidogrel or other medicines used to prevent blood clots from forming (see section 3, "Change of anticoagulant medicine")
- an injection of dextran (used as a blood substitute)
- ibuprofen, diclofenac, ketorolac or other medicines called nonsteroidal anti-inflammatory drugs, which are used to treat pain, swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines that increase the level of potassium in your blood, such as potassium salts, diuretics and certain medicines for heart problems.

### **Surgical and anaesthetic procedures**

If you need to have a spinal or lumbar puncture or a surgical procedure where epidural or spinal anaesthesia is given, tell your doctor that you are using Enoxaparin sodium Impact.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at greater risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breastfeed, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Enoxaparin sodium Impact has no effect on the ability to drive and use machines.

It is advisable to have the trade name and batch number of the product you are using recorded by your healthcare professional.

## **3. HOW TO USE ENOXAPARIN SODIUM IMPACT**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

## **To use this medicine**

- Normally, Enoxaparin sodium Impact will be given to you by your doctor or nurse. Indeed, it must be administered by injection.
- Enoxaparin sodium Impact is usually given by injection under the skin (subcutaneous route).
- Enoxaparin sodium Impact can be administered by injection into your vein (intravenous route) after certain types of myocardial infarction or after an interventional procedure.
- Enoxaparin sodium Impact can be introduced into the arterial line of the dialysis circuit at the start of the session.
- Do not inject Enoxaparin sodium Impact into a muscle.

## **How much will you receive**

- Your doctor will decide how much Enoxaparin sodium Impact to give you. The amount will depend on the reason it is used.
- If you have kidney failure, it is possible that you will receive a lower amount of Enoxaparin sodium Impact.

### **1. Treatment of blood clots in your blood**

- The usual dose is 150 IU (1.5 mg) for each kilogram of your weight once a day or 100 IU (1 mg) for each kilogram of your weight twice a day.
- Your doctor will decide how long you should receive Enoxaparin sodium Impact.

### **2. Prevention of blood clots in your blood during surgical procedures or periods of reduced mobility due to an illness**

- The dose will depend on your risk of developing a clot. You will receive a dose of 2 000 IU (20 mg) or 4 000 IU (40 mg) of Enoxaparin sodium Impact once daily.
- If you need to have a surgical procedure done, your first injection will usually be given 2 hours or 12 hours before your interventional procedure.
- If your mobility is reduced due to an illness, you will normally receive a dose of 4 000 IU (40 mg) of Enoxaparin sodium Impact every day.
- Your doctor will decide how long you should receive Enoxaparin sodium Impact.

### **3. Treatment and prevention of blood clots if you have unstable angina or after a myocardial infarction**

Enoxaparin sodium Impact can be used for two different types of myocardial infarction. The amount of Enoxaparin sodium Impact you will be given will depend on your age and the type of myocardial infarction you have had.

Non-ST-segment elevation myocardial infarction (NSTEMI):

- The usual dose is 100 IU (1 mg) for each kilogram of your weight every 12 hours.
- Normally, your doctor will also prescribe aspirin (acetylsalicylic acid).
- Your doctor will decide how long you should receive Enoxaparin sodium Impact.

Myocardial infarction with ST-segment elevation (STEMI) if you are under 75 years of age:

- An initial dose of 3 000 IU (30 mg) of Enoxaparin sodium Impact will be injected into a vein.
- At the same time, you will also receive Enoxaparin sodium Impact as an injection under the skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for each kilogram of your weight, every 12 hours.
- Normally, your doctor will also prescribe aspirin (acetylsalicylic acid).
- Your doctor will decide how long you should receive Enoxaparin sodium Impact.

ST-segment elevation myocardial infarction (STEMI) if you are over 75 years of age:

- The usual dose is 75 IU (0.75 mg) for each kilogram of your weight every 12 hours.

- The maximum amount of Enoxaparin sodium Impact administered during the first two injections is 7 500 IU (75 mg).
- Your doctor will decide how long you should receive Enoxaparin sodium Impact.

For patients undergoing an operation called a percutaneous coronary intervention (PCI):

Depending on when you will receive your last dose of Enoxaparin sodium Impact, your doctor may decide to administer an additional dose of Enoxaparin sodium Impact before a PCI. This is an injection into your vein.

#### 4. Prevention of blood clots in the dialysis circuit

- The usual dose is 100 IU (1 mg) for each kilogram of your weight.
- Enoxaparin sodium Impact is introduced into the arterial line of the dialysis circuit at the start of the session. The amount is usually sufficient for a 4-hour session. However, your doctor may give you an additional dose of 50 IU to 100 IU (0.5 to 1 mg) for each kilogram of your weight, if necessary.

#### Give yourself an injection of Enoxaparin sodium Impact

If you are able to administer Enoxaparin sodium Impact yourself, your doctor or nurse will show you how to do this. Do not try to give yourself an injection if you have not been trained to do so. If you are unsure of what to do, talk to your doctor or nurse immediately. An injection properly performed under the skin (subcutaneous injection) will help reduce pain and bruising at the injection site.

#### Before administering Enoxaparin sodium Impact

- Collect the items you need: syringe, alcohol swab or soap and water, sharps container.
- Check the expiry date on the medicine. Do not use if the date has passed.
- Check that the syringe is not damaged and that the medicine in the syringe is a clear solution. If this is not the case, use another syringe.
- Make sure you know how much you will inject.
- Check your abdomen to see if the last injection did not cause redness, a change in skin colour, swelling, a secretion discharge or if it is still painful. If this is the case, talk to your doctor or nurse.

#### Instructions for injecting Enoxaparin sodium Impact

##### ***(Instructions for syringes without safety system)***

#### Prepare the injection site

1. Choose an area on the right or left side of your abdomen. It should be at least 5 centimetres from your navel and towards the sides.

- Do not give yourself an injection within 5 centimetres of your navel or around scars or bruises.
- Alternate the injection site between the right side and the left side of your abdomen, depending on the location of the last injection.



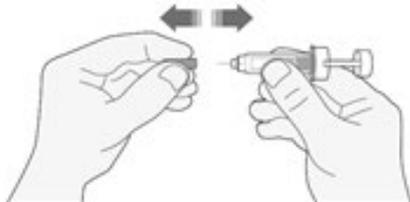
2. Wash your hands. Clean (without rubbing) the chosen area to inject with an alcohol swab or with soap and water.

3. Sit down or lie down in a comfortable position so that you are relaxed. Make sure that you can see the area where you are going to give the injection. A chaise longue, reclining chair or a bed with pillows is ideal.

### Choose your dose

1. Carefully remove the protective cap from the needle. Discard the cap.

- Do not press the plunger to expel any air bubbles before giving yourself the injection. This could lead to a loss of medicine.
- Once you have removed the cap, do not let the needle touch anything. This is to ensure that the needle remains clean (sterile).



2. When the amount of medicine in the syringe already matches the prescribed dose, it is not necessary to adjust the dose. You are now ready for the injection.

3. When the dose depends on your weight, you may need to adjust the dose in the syringe to match the prescribed dose. In this case, you can remove the excess medicine by pointing the syringe down (to keep the air bubble in the syringe) and by removing the excess amount into a container.

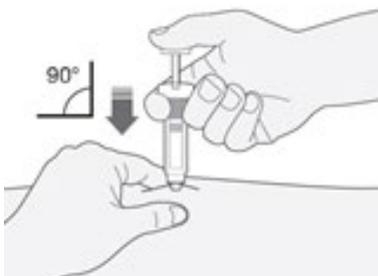
4. The appearance of a drop at the end of the needle is possible. In this case, remove the drop before injection by tapping on the syringe with the needle pointing down. You are now ready for the injection.

### Injection

1. Hold the syringe in the hand you write with (such as a pencil). With your other hand, gently pinch the cleaned area of your abdomen between your index finger and thumb to make a fold in the skin.

- Make sure to keep the skin fold throughout the injection.

2. Hold the syringe so that the needle points down (at a 90° angle to the skin). Insert the entire length of the needle into the skin fold.



3. Press down the plunger with your thumb. This will send the medicine into the adipose tissue of your abdomen. Complete the injection using all the medicine in the syringe.

4. Remove the needle from the injection site by pulling it straight out. Do not point the needle toward you and others. You can now let go of the skin fold.



### When you are done

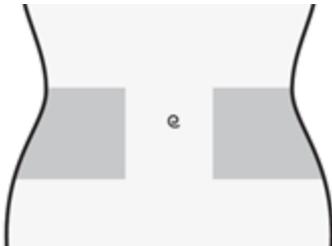
1. To avoid bruising, do not rub the injection site after you have given the injection.
2. Discard the used syringe in the sharps container. Close the lid of the container tightly and place the container out of the reach of children. When the container is full, dispose of it as instructed by your doctor or pharmacist.

Any unused medicinal product or waste material should be disposed of in accordance with applicable regulations.

### ***(Instructions for syringe with the ERIS™ automatic safety system)***

#### Prepare the injection site

1. Choose an area on the right or left side of your abdomen. It should be at least 5 centimetres from your navel and towards the sides.
- Do not give yourself an injection within 5 centimetres of your navel or around scars or bruises.
  - Alternate the injection site between the right side and the left side of your abdomen, depending on the location of the last injection.

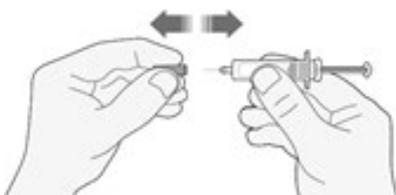


2. Wash your hands. Clean (without rubbing) the chosen area to inject with an alcohol swab or with soap and water.

3. Sit down or lie down in a comfortable position so that you are relaxed. Make sure that you can see the area where you are going to give the injection. A chaise longue, reclining chair or a bed with pillows is ideal.

#### Choose your dose

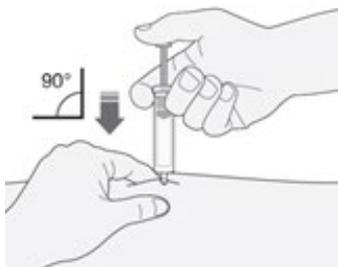
1. Carefully remove the protective cap from the needle. Discard the cap.
- Do not press the plunger to expel any air bubbles before giving yourself the injection. This could lead to a loss of medicine.
  - Once you have removed the cap, do not let the needle touch anything. This is to ensure that the needle remains clean (sterile).



2. When the amount of medicine in the syringe already matches the prescribed dose, it is not necessary to adjust the dose. You are now ready for the injection.
3. When the dose depends on your weight, you may need to adjust the dose in the syringe to match the prescribed dose. In this case, you can remove the excess medicine by pointing the syringe down (to keep the air bubble in the syringe) and by removing the excess amount into a container.
4. The appearance of a drop at the end of the needle is possible. In this case, remove the drop before injection by tapping on the syringe with the needle pointing down. You are now ready for the injection.

## **Injection**

1. Hold the syringe in the hand you write with (such as a pencil). With your other hand, gently pinch the cleaned area of your abdomen between your index finger and thumb to make a fold in the skin.
  - Make sure to keep the skin fold throughout the injection.
2. Hold the syringe so that the needle points down (at a 90° angle to the skin). Insert the entire length of the needle into the skin fold.



3. Press down the plunger with your thumb. This will send the medicine into the adipose tissue of your abdomen. Complete the injection using all the medicine in the syringe.
4. Remove the needle from the injection site by pulling it straight out. A protective sleeve will automatically cover the needle. You can now let go of the skin fold. The safety system only releases the protective sleeve if the syringe has been completely emptied by pressing the plunger all the way down.



## **When you are done**

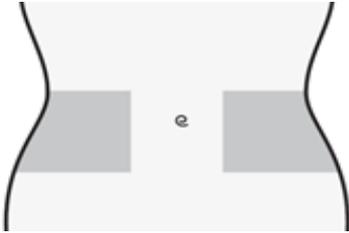
1. To avoid bruising, do not rub the injection site after you have given the injection.
2. Discard the used syringe in the sharps container. Close the lid of the container tightly and place the container out of the reach of children. When the container is full, dispose of it as instructed by your doctor or pharmacist.

Any unused medicinal product or waste material should be disposed of in accordance with applicable regulations.

***(Instructions for syringe with the PREVENTIS™ automatic safety system)***

## Prepare the injection site

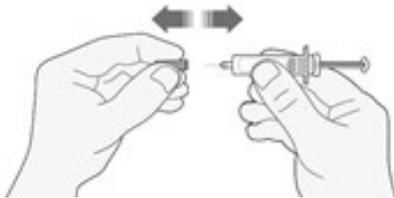
1. Choose an area on the right or left side of your abdomen. It should be at least 5 centimetres from your navel and towards the sides.
  - Do not give yourself an injection within 5 centimetres of your navel or around scars or bruises.
  - Alternate the injection site between the right side and the left side of your abdomen, depending on the location of the last injection.



2. Wash your hands. Clean (without rubbing) the chosen area to inject with an alcohol swab or with soap and water.
3. Sit down or lie down in a comfortable position so that you are relaxed. Make sure that you can see the area where you are going to give the injection. A chaise longue, reclining chair or a bed with pillows is ideal.

## Choose your dose

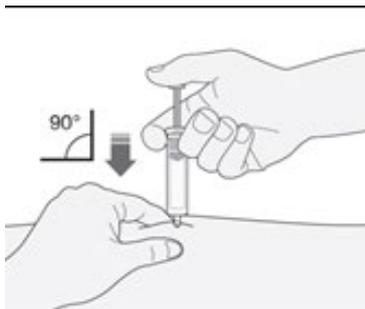
1. Carefully remove the protective cap from the needle. Discard the cap.
  - Do not press the plunger to expel any air bubbles before giving yourself the injection. This could lead to a loss of medicine.
  - Once you have removed the cap, do not let the needle touch anything. This is to ensure that the needle remains clean (sterile).



2. When the amount of medicine in the syringe already matches the prescribed dose, it is not necessary to adjust the dose. You are now ready for the injection.
3. When the dose depends on your weight, you may need to adjust the dose in the syringe to match the prescribed dose. In this case, you can remove the excess medicine by pointing the syringe down (to keep the air bubble in the syringe) and by removing the excess amount into a container.
4. The appearance of a drop at the end of the needle is possible. In this case, remove the drop before injection by tapping on the syringe with the needle pointing down. You are now ready for the injection.

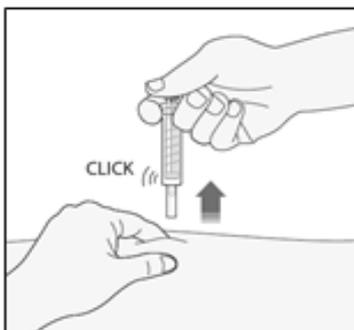
## Injection

1. Hold the syringe in the hand you write with (such as a pencil). With your other hand, gently pinch the cleaned area of your abdomen between your index finger and thumb to make a fold in the skin.
  - Make sure to keep the skin fold throughout the injection.
2. Hold the syringe so that the needle points down (at a 90° angle to the skin). Insert the entire length of the needle into the skin fold.



3. Press down the plunger with your thumb. This will send the medicine into the adipose tissue of your abdomen. Complete the injection using all the medicine in the syringe.
4. Remove the needle from the injection site by pulling it straight out while keeping your fingers on the plunger. Move the needle away from you and from others and press firmly down on the plunger to activate the safety system. The protective sleeve will automatically cover the needle. You will hear an audible "click" to confirm the activation of the protective sleeve. You can now release the skin fold.

]



### When you are done

1. To avoid bruising, do not rub the injection site after you have given the injection.
2. Discard the used syringe in the sharps container. Close the lid of the container tightly and place the container out of the reach of children. When the container is full, dispose of it as instructed by your doctor or pharmacist.

Any unused medicinal product or waste material should be disposed of in accordance with applicable regulations.

### Change of anticoagulant medicine

- **Switching from a treatment with Enoxaparin sodium Impact to anticoagulants called vitamin K antagonists (such as warfarin)**  
Your doctor will ask you to have blood tests called an INR and will tell you when to stop Enoxaparin sodium Impact.
- **Switching from a treatment with anticoagulants called vitamin K antagonists (such as warfarin) to Enoxaparin sodium Impact**  
Stop taking the vitamin K antagonist. Your doctor will ask you to have blood tests called an INR and will tell you when to start Enoxaparin sodium Impact.
- **Switching from a treatment with Enoxaparin sodium Impact to a treatment with a direct oral anticoagulant**  
Stop taking Enoxaparin sodium Impact. Start taking the direct oral anticoagulant within 2 hours before the time you should have received the next injection, then continue with the normal treatment.
- **Switching from a treatment with a direct oral anticoagulant to Enoxaparin sodium Impact**  
Stop taking the direct oral anticoagulant. Wait 12 hours after the last dose of the direct oral anticoagulant before starting the treatment with Enoxaparin sodium Impact.

### **If you use more Enoxaparin sodium Impact than you should**

If you think you have used too much or too little Enoxaparin sodium Impact, tell your doctor, pharmacist or nurse immediately, even if you do not have any signs. If a child accidentally injects or swallows Enoxaparin sodium Impact, take him/her immediately to the emergency room of a hospital.

### **If you forget to use Enoxaparin sodium Impact**

If you forget to give yourself a dose, take it as soon as you remember. Do not take a double dose on the same day to make up for a forgotten dose. Making a note on a diary or notebook will help you not miss a dose.

### **If you stop using Enoxaparin sodium Impact**

It is important that you continue to receive injections of Enoxaparin sodium Impact until your doctor decides to stop them. If you stop the treatment, you may develop a blood clot that can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Serious side effects**

**Stop using Enoxaparin sodium Impact and tell a doctor or nurse immediately** if you experience any sign of a severe allergic reaction (such as a skin rash, difficulty breathing or swallowing, swelling of face, lips, tongue, oral cavity, throat or eyes).

**Stop using Enoxaparin sodium Impact and see a doctor immediately** if you notice any of the following symptoms:

- an extensive, red, scaly skin rash with bumps under the skin and blisters with fever. Symptoms usually appear at the start of treatment (acute generalised exanthematous pustulosis).

Like other similar medicines (decreasing blood clotting), Enoxaparin sodium Impact can cause bleeding. This can be life-threatening. In some cases, bleeding may not be visible.

### **Tell your doctor immediately if:**

- you have any bleeding that does not stop on its own
- you have signs of excessive bleeding such as being very weak, tired, pale or dizziness with headache or unexplained swelling.

Your doctor may decide to keep you under close monitoring or change your treatment.

### **Tell your doctor immediately:**

- if you have signs of blood vessel obstruction by a clot, such as:
  - cramping, redness, warmth or swelling in one of your legs: these are symptoms of deep vein thrombosis.
  - breathlessness, chest pain, loss of consciousness or coughing up blood: these are symptoms of pulmonary embolism.
- if you have a painful skin rash with dark red spots under the skin, which do not disappear if you press on them.

Your doctor may ask you to have a blood test to check your platelet count.

### **Other side effects**

Very common (may affect more than 1 in 10 people):

- bleeding
- increased hepatic enzyme levels.

Common (may affect up to 1 in 10 people):

- you bruise more than usual – this could be due to a blood problem caused by a low platelet count
- pink spots on the skin – they are more likely to appear around the area where Enoxaparin sodium Impact was injected
- skin rash (urticaria)
- red itchy skin
- bruising or injection site pain
- decreased number of red blood cells
- high number of platelets in the blood
- headaches.

Uncommon (may affect up to 1 in 100 people):

- severe headache that comes on suddenly - this could be a sign of bleeding in the brain
- feeling of tenderness and swelling in the stomach - you may be bleeding from the stomach
- large, irregular shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of the skin or eyes and your urine becomes darker. This could be a liver problem.

Rare (may affect up to 1 in 1 000 people):

- severe allergic reaction - the signs may include: skin rash, difficulty swallowing or breathing, swelling of lips, face, throat or tongue
- increased levels of potassium in your blood - it is more likely that this will occur in people with kidney problems or diabetes. Your doctor may check this by doing a blood test
- an increase in the number of eosinophils in your blood - your doctor may check this by doing a blood test
- hair loss
- osteoporosis (a condition that makes your bones more likely to break) after long-term use
- tingling, numbness and muscle weakness (especially in the lower part of your body) when you have had a lumbar puncture or anaesthesia in your spine
- difficulty controlling your bladder or intestines (you cannot control yourself when you go to the bathroom)
- hard nodule or bump at the injection site.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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

## **5. HOW TO STORE ENOXAPARIN SODIUM IMPACT**

Store below 25°C. Do not freeze.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice a defect in the syringe, particles in the solution or an abnormal colour of the solution (see “What Enoxaparin sodium Impact looks like and contents of the pack”).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Enoxaparin sodium Impact contains**

- The active substance is: enoxaparin sodium.  
Each ml contains 100 mg of enoxaparin sodium, corresponding to 10 000 IU of anti-Xa activity.  
One 0.4 ml pre-filled syringe contains 4 000 IU (40 mg) of enoxaparin sodium.  
One 0.6 ml pre-filled syringe contains 6 000 IU (60 mg) of enoxaparin sodium.  
One 0.8 ml pre-filled syringe contains 8 000 IU (80 mg) of enoxaparin sodium.
- The other ingredient is: water for injection.

### **What Enoxaparin sodium Impact looks like and contents of the pack**

Enoxaparin sodium Impact is a clear, colourless to yellowish solution for injection in a pre-filled glass syringe (with or without an automatic safety system).

Boxes of 2, 5, 6, 10, 12, 20, 24, 30, 50, 100 pre-filled syringes and in multipacks of 3 x 10, 9 x 10, 100 x 10 and 200 x 10 pre-filled syringes.

Not all pack sizes may be marketed.

### **Conditions of prescription and issuance**

List I

### **Marketing authorization holder**

Sanofi-Aventis France  
82 avenue Raspail  
94250 Gentilly  
France

### **Manufacturer**

Sanofi Winthrop Industrie  
180 rue Jean Jaures  
94700 Maisons-Alfort  
France

**This leaflet was last revised in November 2022.**

For updated leaflet in your country language: <http://qr.impact.sanofi/enoxaparin> or scan the QR Code on the outer carton.