Lovenox® 6000 anti-Xa IU/0,6 ml
Lovenox® 8000 anti-Xa IU/0,8 ml
Lovenox® 10000 anti-Xa IU/1 ml

Enoxaparin sodium

Solution for injection in prefilled syringes with safety device

Read all of this leaflet carefully before you start using this medicine.
This leaflet contains important information about your treatment.
If you have further questions, or any doubts, please ask your doctor or your pharmacist for more information.
This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
Keep this leaflet. You may need to read it again.

WHAT IS LOVENOX?

COMPOSITION
Lovenox 6 000 anti-Xa IU/0.6 ml:
Enoxaparin sodium . ..... 6 000 anti-Xa IU, i.e. 60.0 mg
for one prefilled syringe with safety device.
Water for injection ..... q.s. 0.6 ml
Lovenox 8 000 anti-Xa IU/0.8 ml:
Enoxaparin sodium ... 8 000 anti-Xa IU, i.e. 80.0 mg
for one prefilled syringe with safety device.
Water for injection . ..... q.s. 0.8 ml
Lovenox 10000 UI anti-Xa/1 ml :
Enoxaparin sodium ..... 10000 anti-Xa IU, i.e. 100.0 mg
for one prefilled syringe with safety device.
Water for injection .... .. q.s. 1 ml

PHARMACEUTICAL FORM
Solution for injection in prefilled syringes with safety device.
Boxes of 2 or 10 prefilled syringes with safety device.
Some presentations may not be marketed.

PHARMACOTHERAPEUTIC GROUP
Antithrombotic agent

NAME AND ADDRESS OF OPERATING COMPANY
sanofi-aventis france
1-13, boulevard Romain Rolland
75014 PARIS
France

NAME AND ADDRESS OF MANUFACTURER
SANOFI WINTHROP INDUSTRIE
Boulevard Industriel, Zone Industrielle
76580 Le Trait
France

WHAT IS LOVENOX USED FOR?

This medicinal product is an anticoagulant agent of the so-called low-molecular-weight heparin family. It prevents blood clots from forming in a vein or artery (*thrombosis*) and also prevents recurrence.

A low-molecular-weight heparin can be prescribed:
- as preventive treatment, to avoid formation of blood clots,
- as curative treatment, when a blood clot has already formed.

This medicinal product is used to treat:
- blood clot in a vein (*venous thrombosis*) with or without pulmonary embolism,
- certain types of coronary artery disease,
- myocardial infarction treated by a thrombolytic agent (medicine that helps blood clots to dissolve).

BEFORE TAKING LOVENOX

WHEN NOT TO USE THIS MEDICINAL PRODUCT
Do not use LOVENOX if any of the following apply:

Use of this medicine is CONTRAINDICATED

- if you have a known allergy to the medicinal product, to heparin or heparin derivatives, including other low-molecular-weight heparins,
- if you have previously had a serious decrease in platelets due to heparin (platelets play an important role in blood clotting),
- if you have a known blood clotting disorder,
- if you have any lesions (internal or external) likely to bleed.
- cerebral hemorrhage,
- if you have severe renal failure (except hemodialysis),
- spinal/epidural anesthesia is contraindicated during curative treatment,
- if you have excessive bleeding.

Use of this medicine is NOT RECOMMENDED

- in combination with: aspirin (at doses used for pain and fever), non-steroidal anti-inflammatory drugs (NSAIDs) or dextran (a drug used in intensive care)
- during the first days following a stroke without hemorrhage,
- most types of endocarditis (heart infections),
- mild to moderate renal failure

SPECIAL WARNINGS
In order to avoid bleeding, it is essential not to exceed the dose and duration of treatment that your physician has prescribed (see 3.c Precautions for use).

Treatment requires repeated blood tests to regularly check your platelet count (generally twice a week).

During heparin treatment, a significant decrease in the number of platelets may occur in very rare cases. This requires discontinuation of heparin treatment and increased monitoring as there may be serious complications, particularly thrombosis, paradoxically.

This medicinal product is generally not recommended in children.

DO NOT INJECT BY THE INTRAMUSCULAR ROUTE. The instructions for injection must be strictly respected.

PRECAUTIONS FOR USE
As with all anticoagulants, bleeding may occur. In the event of bleeding, the cause must be identified and appropriate treatment instituted.
In some cases, particularly in curative treatment, there may be a risk of bleeding:
- elderly patients,
- bodyweight below 40 kg,
- kidney failure,
- if treatment is continued beyond the usual duration of 10 days,
- in combination with certain medicines (see 3.d Interactions with other drugs and other interactions),
- in combination with certain medicines which increase the risk of bleeding (see 3.d Interactions with other drugs and other interactions).

These situations may require particular monitoring: medical examinations and possibly blood samples.

If you currently have or have previously suffered from liver or kidney disease, an ulcer or other lesions likely to bleed, inform your physician.

INTERACTIONS WITH OTHER DRUGS AND OTHER INTERACTIONS
Due to the possible occurrence of bleeding, always inform your doctor if you are taking one of the following drugs:
- aspirin,
- non-steroidal anti-inflammatory drugs (NSAIDs),
- platelet aggregation inhibitors (abciximab, eptifibatide, iloprost, ticlopidine, tirofiban),
- dextran (*drug used in intensive care*),
- oral anticoagulants (which inhibit vitamin K).

TO AVOID POSSIBLE INTERACTIONS BETWEEN MEDICINAL PRODUCTS, ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU ARE TAKING.

Your doctor may adjust your treatment accordingly.

PREGNANCY AND BREAST-FEEDING
Pregnancy
Use of this medicinal product is not recommended during pregnancy.
If you find that you are pregnant during treatment, consult your doctor as only he or she can evaluate the need to continue treatment.

Breast-feeding
This medication is not contraindicated in breast-feeding women.

AS A GENERAL RULE, IF YOU ARE PREGNANT OR BREAST-FEEDING, YOU SHOULD ALWAYS INFORM YOUR DOCTOR OR PHARMACIST BEFORE YOU USE A MEDICINE.

HOW TO USE LOVENOX

HOW MUCH LOVENOX SHOULD BE USED?
Dosage and duration of treatment are determined by your physician according to your bodyweight and the therapeutic indication.
In general, the dosage is 100 anti-Xa IU/kg every 12 hours.
To treat myocardial infarction, an initial intravenous injection of 3000 anti-Xa IU is required.

In patients treated for certain types of angina and myocardial infarction, Lovenox is combined with an oral dose of aspirin, taken once daily.

1 ml of solution for injection is equivalent to about 10 000 anti-Xa IU of enoxaparin.

If this medicine is to be replaced by an anticoagulant taken orally, the injections will only be stopped after a few days during which you will receive both treatments. This corresponds to the time needed for the second medicine to become active and for blood coagulation values to reach the appropriate level as determined by your physician.

To treat myocardial infarction in patients aged over 75, the dosage is reduced to 75 anti-Xa IU/kg every 12 hours, with no initial IV injection.

HOW IS LOVENOX ADMINISTERED?
SUBCUTANEOUS INJECTION (except for patients treated for myocardial infarction for whom an initial IV injection is required).
Do not inject by the intramuscular route.

WHEN AND HOW OFTEN SHOULD LOVENOX BE USED?
Two injections daily, twelve hours apart.

HOW LONG SHOULD LOVENOX BE USED?
- Venous thrombosis: treatment should generally not exceed 10 days
- Certain types of angina: treatment lasts 2 to 8 days, until stabilization
- In myocardial infarction, the recommended treatment duration is 8 days, or until discharge from hospital if the hospitalization period is less than 8 days.

WHAT SHOULD BE DONE IN CASE OF OVERDOSE?
Contact a physician quickly due to the risk of bleeding.

UNWANTED AND UNPLEASANT EFFECTS

AS WITH ALL MEDICINAL PRODUCTS, THIS SUBSTANCE MAY HAVE EFFECTS WITH VARYING DEGREES OF DISCOMFORT IN SOME PATIENTS.
- Bleeding of varying seriousness, external or internal. You must immediately inform the physician or the nurse. Bleeding may be promoted by lesions that are likely to bleed, by kidney failure or by certain drugs taken at the same time.
- Decrease in the number of platelets in the blood which may be serious in some cases and which must immediately be reported to the treating physician (see 3.b Special Warnings). This is why platelet counts need to be checked regularly. Reversible increases in the number of platelets have also been reported.
- Rare severe skin reactions at the injection site.
- Frequently, bruises may appear or nodules (small lumps) may be felt under the skin at the injection site, and this may cause varying degrees of pain. These effects will disappear naturally and are not cause to discontinue treatment.
- Local or general allergic reactions.
- Risk of osteoporosis (skeletal demineralization leading to bone fragility) in prolonged treatment.
- Other effects: increased number of certain liver enzymes in the blood, increased blood potassium, increased in the number of certain white blood cells (eosinophils) which can occur in isolated cases or along with skin effects.
- In rare cases, neurological injury of varying seriousness has been reported following administration of this kind of medication during certain types of anesthesia.
- Very rare case of allergy-induced inflammation of small blood vessels have been reported.

INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNWANTED OR UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

STORING LOVENOX

DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING
SPECIAL PRECAUTIONS FOR STORAGE
Store at a temperature below 25°C. This medicine is to be stored in its packaging until use.

THIS LEAFLET WAS LAST REVISED IN

January 2009

INSTRUCTIONS FOR THE PERSON ADMINISTERING LOVENOX

Using the syringes fitted with a safety device/subcutaneous injection technique: To avoid accidental needle sticks after injection, the prefilled syringes are fitted with an automatic safety device.

- Take the protective cap off the needle.
- Adjust the dose to be injected (if necessary):
  The amount of medicine to be injected must be adjusted depending on the patient's body weight; therefore any excess medicine must be expelled before injection by holding the syringe pointing down (to keep the air bubble in the syringe). If it is not expelled, the safety device will not be activated at the end of injection.
  When there is no excess medicine, this step is not necessary.
  A drop may appear at the tip of the needle. If this occurs, remove the drop before injection by tapping on the syringe, with the needle pointing downwards.

- Administer the injection:
  The injection must be given with the patient preferably lying down, in the subcutaneous tissue of the anterolateral or posterolateral abdominal wall, alternating between the left and right sides.
  The needle should be introduced **perpendicularly**, not from the side, into a skin fold held between the thumb and index finger. **This skin fold should be held throughout the injection.**

- The safety device is activated automatically **once the plunger is fully pressed down**, thus completely protecting the used needle without causing discomfort to the patient.
  The plunger has to be pressed down all the way for the safety device to be activated.
  Note: **The safety device can only be activated once the syringe is completely empty.**