# Lovenox® 2000 anti-Xa IU/0,2 ml
# Lovenox® 4000 anti-Xa IU/0,4 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 2 000 anti-Xa IU/0.2 ml:**
Enoxaparin sodium.. ..... 2 000 anti-Xa IU, i.e. 20.0 mg
for one prefilled syringe with safety device
Water for injection... ..... q.s. 0.2 ml
**Lovenox 4 000 anti-Xa IU/0.4 ml:**
Enoxaparin sodium ..... 4 000 anti-Xa IU, i.e. 40.0 mg
for one prefilled syringe with safety device
Water for injection... . ..... q.s. 0.4 ml

**PHARMACEUTICAL FORM**
Solution for injection in prefilled syringes with safety device.
Boxes of 2, 6 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 medicine is used in specific cases, in surgery or medicine (**this indication is specific to Lovenox 4 000 anti-Xa IU/0.4 ml**) in patients with a risk of venous disease (blood clot in a vein).
It is also used to prevent coagulation in dialysis machine tubing *(in patients with kidney failure)*.

BEFORE TAKING LOVENOX

**WHEN NOT TO USE THIS MEDICINAL PRODUCT**
LOVENOX should not be used 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.
- if you have excessive bleeding

Use of this medicine is NOT RECOMMENDED

- if you have severe kidney failure,
- during the first 24 hours following brain hemorrhage,
- **if you are over 65 years of age,** in combination with aspirin (at doses used for pain and fever), non-steroidal anti-inflammatory drugs or dextran.

**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 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.

Prevention of venous thrombosis in patients bedridden for acute medical conditions **(this is specific to Lovenox 4 000 anti-Xa IU/0.4 ml)**
In patients with acute infection or acute rheumatic disease, treatment is only warranted if one of the following applies to you: patient aged over 75 years, tumor, history of venous disease, obesity, hormone treatment, heart failure or chronic respiratory failure.
This medicinal product is generally not recommended in children.
Use of this medicine for the prevention of thrombo-embolic events is not recommended in patients, particularly pregnant women, who have a mechanical prosthetic heart valve.
DO NOT INJECT BY THE INTRAMUSCULAR ROUTE. The instructions for injection must be strictly followed.

**PRECAUTIONS FOR USE**
As with all anticoagulants, bleeding may occur. If bleeding occurs, the cause must be identified and appropriate treatment started.
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 Interactions with other drugs and other interactions),
- in combination with certain medicines which increase the risk of bleeding (see Interactions with other drugs and other interactions).

These situations may require particular monitoring: medical examinations and possibly blood samples.
Epidural or spinal anesthesia is not contraindicated when this medicine is given preventively. However, certain precautions must be taken: interval between the injection and the anesthesia, specific monitoring.
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**
It is preferable not to use this medicine during the 1st trimester of pregnancy. During the 2nd and 3rd trimesters, the drug will only be used if your doctor considers it necessary.
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 MUCH LOVENOX SHOULD BE USED?**
Dosage depends on the indication and the patient.
- Preventive treatment in surgery:
  - Moderate-risk surgery: dosage is one daily injection of 2 000 anti-Xa IU/0.2 ml (20 mg/0.2 ml).
  - High-risk surgery: hip and knee surgery:
    Dosage is one daily injection of 4 000 anti-Xa IU/0.4 ml (40 mg/0.4 ml)
- Hemodialysis: one 100 anti-Xa IU/kg dose will be administered.
- Preventive treatment in medicine: (**specific to Lovenox 4 000 anti-Xa IU/0.4 ml**):
  Dosage is one daily injection of 4 000 anti-Xa IU/0.4 ml (40 mg/0.4 ml)

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 doctor.

**HOW IS LOVENOX ADMINISTERED?**
SUBCUTANEOUS INJECTION (except when used for dialysis).
Do not inject by the intramuscular route.

**WHEN AND HOW OFTEN SHOULD LOVENOX BE USED?**
- Prevention: 1 injection daily,
- Hemodialysis: the drug is injected directly into the arterial line of the hemodialysis tubing, at the beginning of the dialysis session.

**HOW LONG SHOULD LOVENOX BE USED?**
**Lovenox 2 000 anti-Xa IU/0.2 ml:**
In general, treatment does not last more than 10 days.
**Lovenox 4 000 anti-Xa IU/0.4 ml:**
- In general surgery, treatment does not usually last more than 10 days, except when prescribed after certain hip operations.
- In patients with acute medical conditions, treatment duration is 6 to 14 days. There are currently no data justifying treatment for longer than 14 days.

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

*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 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 stop 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 allergic inflammation of small blood vessels have been reported.

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

**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.

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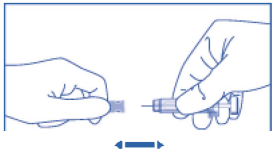
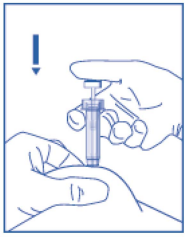
**Using the syringes fitted with a safety device/subcutaneous injection technique:**
To avoid accidental needle sticks after injection, the prefilled syringes are fitted with an automatic safety device.

- Take the protective cap off the needle.
  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 prefilled syringe is ready to use. Do not expel any air from the syringe before administering 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**.