

ENOXAMED®

2000 IU anti-Xa (20 mg) / 0.2 ml
4000 IU anti-Xa (40 mg) / 0.4 ml
6000 IU anti-Xa (60 mg) / 0.6 ml
8000 IU anti-Xa (80 mg) / 0.8 ml
10000 IU anti-Xa (100 mg) / 1 ml

Enoxaparin sodium
Solution for injection S.C. / Intravascular way

Read this leaflet carefully before you start using this medicine
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effect gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, health care provider or your pharmacist.

- In this leaflet:
- 1. What ENOXAMED® is and what it is used for
 - 2. Before you use ENOXAMED®
 - 3. How to use ENOXAMED®
 - 4. Possible side effects
 - 5. How to store ENOXAMED®
 - 6. Further information

1. What ENOXAMED® is and what it is used for:
■ **Pharmacotherapeutic group:**
Antithrombotic drug, belonging to the heparin group of low molecular weight (LMWH).
■ **Therapeutic indications:**
ENOXAMED® is indicated in the adult in:
- Prophylactic treatment of venous thromboembolic disease in moderate and high-risk surgery, particularly in orthopedic or general surgery, including oncological surgery.
- Prophylactic treatment of venous thromboembolic disease in patients with an acute medical condition (such as acute heart failure, respiratory failure, severe infections or rheumatic diseases) and whose mobility is reduced, at increased risk of venous thromboembolism.
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to be a thrombolytic or surgical treatment.
- Preventing the formation of a thrombus in the extracorporeal circulation circuit during hemodialysis.
- The acute coronary syndrome:
- Treatment of unstable angina and myocardial infarction without ST segment elevation (NSTEMI), administered in combination with acetylsalicylic acid through the oral way.
- Treatment of acute myocardial infarction with ST segment elevation (STEMI), including patients eligible for secondary medical treatment or percutaneous coronary intervention (PCI).

2. Before you use ENOXAMED®:
a. Do not use ENOXAMED®:
Do never use ENOXAMED® if:
- You are allergic to:
- enoxaparin sodium;
- Heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin.
Signs of allergic reaction include: skin rash, difficulty in breathing or swallowing, swelling of the face, lips, mouth, throat or eyes.
- You have had a reaction to heparin which has caused your coagulation cell (platelet) count to decrease significantly in the last 100 days.
- you have antibodies to enoxaparin in your blood
- you are bleeding profusely or you have a condition associated with a high risk of bleeding such as:
- A stomach ulcer, recent brain or eye surgery, or a recent hemorrhagic stroke.
- You are using ENOXAMED® to treat blood clots and must be tested within 24 hours:
- A spinal or lumbar puncture
- Surgery with spinal anesthesia or epidural anesthesia.
Do not use ENOXAMED® if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using ENOXAMED®.
b. Take special care with ENOXAMED®:
ENOXAMED® 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.
- Tell your doctor or pharmacist before using ENOXAMED® if you have ever had a reaction to heparin which caused a significant decrease in the number of clotting cells (platelets); if you wear a heart valve; if you have endocarditis (an infection of the inner lining of the heart); if you have a history of stomach ulcer; if you have had a recent stroke; if you have high blood pressure; if you have diabetes or have problems with the blood vessels in the eye caused by diabetes (called diabetic retinopathy);

if you have recently had eye or brain surgery; if you are elderly (over 65) and in particular if you are over 75; if you have kidney failure; if you have liver failure; if you are underweight or overweight; if you have a high level of potassium in your blood (this can be checked by a blood test); if you are currently using drugs that increase the risk of bleeding; if you have a problem with your spine or have had surgery on your spine. If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using ENOXAMED®.

Tests and controls
You may need to have a blood test before starting 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 efficiency of ENOXAMED® have not been evaluated in children or adolescents.

- c) Taking other medicines, herbal or dietary supplements:**
Tell your doctor or pharmacist if you are taking or might take any other medicines such as:
- Warfarin (used to thin the blood).
- Aspirin (also called acetylsalicylic acid or ASA), clopidogrel or other medicines used to prevent blood clots.
- 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 potassium level in your blood, such as potassium salts, diuretics and some medicines for heart problems

Surgical and anesthetic interventions:
If you are going to have a spinal or lumbar puncture or surgery during which an epidural or spinal anesthesia is performed, tell your doctor that you are using ENOXAMED®.

- d. Using ENOXAMED® with food and drinks:** Nothingness.
e. Pregnancy and breast-feeding:
If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If you are pregnant and wear a mechanical heart valve, you may be at a higher risk of developing blood clots. Your doctor should tell you about it.
If you are breast-feeding or planning to breast-feed, ask your doctor or pharmacist for advice before taking this medication.
f. Driving and using machines: Nothingness.
g. How to use ENOXAMED®:

■ **Posology:**
Always take this medication exactly as instructed by your doctor or pharmacist. Check with your doctor or pharmacist in case of doubt.
Use this medication
- Normally, ENOXAMED® will be given to you by your doctor or nurse. Indeed, it must be administered by injection.
- ENOXAMED® is generally administered by injection under the skin (subcutaneous route).
- ENOXAMED® can be given by injection into your vein (intravenously) after some types of myocardial infarction or after surgery.
- ENOXAMED® can be introduced into the arterial line of the dialysis circuit, at the beginning of the session.
- Do not inject ENOXAMED® into a muscle.

How much you will receive
- Your doctor will decide how much ENOXAMED® to give you. The amount will depend on the reason for which it is used.
- If you have kidney failure, you may receive less ENOXAMED®.

- 1. Prevention of blood clots in your blood:**
- The usual dose is 150 IU (1.5 mg) for each kilogram of your weight once daily or 100 IU (1 mg) for each kilogram of your weight twice daily.
- Your doctor will decide how long you should receive ENOXAMED®.

- 2. Prevention of blood clots in your blood during surgery or periods of reduced mobility due to illness:**
- The dose will depend on your risk of developing a clot. You will receive a dose of 2000 IU (20 mg) or 4000 IU (40 mg) of ENOXAMED® once daily.
- If you need to have surgery, your first injection will usually be given 2 hours or 12 hours before your surgery.
- If your mobility is reduced due to illness, you will normally receive a dose of 4000 IU (40 mg) of ENOXAMED® every day.
- Your doctor will decide how long you should receive ENOXAMED®.

3. Treatment and prevention of blood clots if you have unstable angina or after a myocardial infarction:
ENOXAMED® can be used for two different types of myocardial infarction. The amount of ENOXAMED® you will be given will depend on your age and the type of myocardial infarction you have had.
Myocardial infarction without ST segment elevation (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 ENOXAMED®.
Myocardial infarction with ST segment elevation (STEMI) if you are under the age of 75:
- An initial dose of 3000 IU (30 mg) of ENOXAMED® will be injected into a vein.

- At the same time, you will also receive ENOXAMED® 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 ENOXAMED®.
- Myocardial infarction with ST segment elevation (STEMI) if you are over 75 years:
- The usual dose is 75 IU (0.75 mg) for each kilogram of your weight every 12 hours.
- The maximum amount of ENOXAMED® administered during the first two injections is 7500 IU (75 mg).
- Your doctor will decide how long you should receive ENOXAMED®.
- For patients undergoing an operation called percutaneous coronary intervention (PCI):
Depending on when you receive your last dose of ENOXAMED®, your doctor may decide to give an additional dose of ENOXAMED® before a PCI. It 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.
- ENOXAMED® is introduced into the arterial line of the dialysis circuit, at the beginning of the session. The quantity is generally sufficient for a 4 hours 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.

• **Method of administration:**
Give yourself an injection of ENOXAMED®
If you are able to use ENOXAMED® yourself, your doctor or nurse will show you how. Do not try to give yourself the injection if you have not been trained to do so. If you are not sure what to do, talk to your doctor or nurse immediately. A properly done injection under the skin (subcutaneous injection) will help reduce pain and bruising at the injection site.

Before using ENOXAMED®:
- Gather the items you need: syringe, alcohol swab or soap and water, sharps container.
- Check the expiry date on the medication. Do not use it if the date has passed.
- Check that the syringe is not damaged and that the syringe contains a clear solution. If not, use another syringe.
- Make sure you know how much you are going to inject.
- Check your abdomen to see if the last injection did not cause redness, a change in skin color, swelling, oozing, or if it is still painful. If so, talk to your doctor or nurse.

Instructions to inject ENOXAMED®
Prepare the site of injection
1. Choose an area on the right or left side of your abdomen. It should be at least 5 centimeters from your navel and to the sides.
- Do not inject yourself within 5 centimeters around your navel or around scars or bruises.
- Alternate the injection area between the right side and the left side of your abdomen, depending on where you last injected.
2. Wash your hands. Clean (without rubbing) the area chosen for the injection with an alcohol swab, or soap and water.
3. Sit or lie down in a comfortable position so that you are relaxed. Make sure you can see the area where you are going to give the injection. A lounge chair, a recliner or a raised bed with pillows is ideal.

- Choose your dose**
1. Carefully remove the protective cap from the needle. Throw away the cap.
- Do not press the plunger to expel air bubbles before you inject. This could lead to loss of medication.
- Once you have removed the cap, do not let the needle touch anything. This is to make sure the needle remains clean (sterile).
2. When the medicine amount in the syringe already matches the prescribed dose, there is no need to adjust the dose. You are now ready for 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 dispose of the excess medicine by pointing the syringe down (to keep the air bubble in the syringe) and disposing of the excess amount in a container.
4. The appearance of a drop at the end of the needle is possible. In this case, remove the drop before the injection by tapping the syringe with the needle pointing down. You are now ready for injection.

Injection
1. Hold the syringe in the hand you are writing with (like a pencil). With the other hand, gently pinch the cleaned area of your abdomen between your index finger and your thumb to make a fold in the skin.
- Make sure to keep the skin fold for the duration of the injection.
2. Hold the syringe so that the needle points down (at a 90° angle to the skin). Insert the full length of the needle into the fold of the skin.
3. Press the plunger with your thumb. This will send the medication into the fatty tissue of your abdomen. Finish the injection using all the medicine from the syringe.
4. Withdraw the needle from the injection site by pulling it straight out. Do not point the needle towards yourself and others. You can now let go of the fold of the skin.

Once you have finished
1. To avoid bruising, do not rub the injection site after you have given yourself the injection.

2. Dispose of the used syringe in the sharps container. Hermetically close the container lid and place the container out of the reach of children. When the container is full, dispose of it according to the instructions of your doctor or pharmacist.
Change in anticoagulant medication
• **Switching from treatment with ENOXAMED® to anticoagulants called antivitamin K (such as warfarin).**
Your doctor will ask you to do blood tests called INR and will tell you when to stop ENOXAMED®.
• **Switching from treatment with anticoagulants called antivitamin K (such as warfarin) to ENOXAMED®.**
Stop taking anti-vitamin K. Your doctor will ask you to do blood tests called INR and will tell you when to start ENOXAMED®.
• **Transition from treatment with ENOXAMED® to treatment with direct oral anticoagulant**
Stop taking ENOXAMED®. Start taking the direct oral anticoagulant within 2 hours before you should have received the next injection and then continue treatment normally.

• **Switching from a direct oral anticoagulant treatment to ENOXAMED®**
Stop taking the direct oral anticoagulant. Wait 12 hours after the last dose of the direct oral anticoagulant before starting treatment with ENOXAMED®.
a. If you use more ENOXAMED® than you should
If you think you have used too much or too little ENOXAMED®, tell your doctor, pharmacist or nurse immediately, even if you have no signs.
If a child accidentally injects or swallows ENOXAMED®, take him immediately to a hospital emergency department.
Signs and symptoms: accidental overdose after IV, extracorporeal or SC administration of enoxaparin sodium could lead to bleeding complications. Following oral administration of even massive doses, it is unlikely that enoxaparin sodium will be absorbed.
However, even at high doses of protamine, the anti-Xa activity of enoxaparin sodium is never completely neutralized (around 60% at most) (see prescription information for protamine salts).

b. If you forget to use ENOXAMED®
If you forget to give yourself a dose, take it as soon as you remember. Do not give yourself a double dose on the same day to make up for a missed dose. The mention on an agenda or a notebook will help you not to miss a dose.

c. If you stop using ENOXAMED®
It is important that you continue to receive ENOXAMED® injections until your doctor decides to stop them. If you stop treatment, you could develop a blood clot which can be very dangerous.

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

4. Possible side effects:
Like all medications, ENOXAMED® can cause side effects, although not everybody gets them.
Severe side effects
Stop using ENOXAMED® and tell a doctor or nurse immediately if you have any signs of a severe allergic reaction (such as a rash, difficulty in breathing or swallowing, swelling of the face, lips, mouth, throat or eyes). Like other similar medicines (that lowers blood clotting) ENOXAMED® can cause bleeding. It can be life-threatening. In some cases, the 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 having dizziness with unexplained headache or swelling.
Your doctor may decide to keep you under close supervision or change your treatment.

Tell your doctor immediately:
- If you have signs of a clot blocking a blood vessel, such as:
- Cramp-like pain, redness, warmth or swelling in one of your legs: these are symptoms of deep vein thrombosis.
- Breath-shortness, chest pain, unconsciousness or bloody cough: these are symptoms of pulmonary embolism.
- If you have a painful rash of dark red pimples under the skin, which will not go away if you press 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 liver enzyme levels.
Common (may affect up to 1 in 10 people):
- You have more bruises than usual - this could be due to a blood problem caused by low platelet count.
- Pink spots on the skin - they are more likely to appear around the area where ENOXAMED® was injected.
- Skin rash (hives); itchy red skin; bruising or pain at the injection site; decrease in the number of red blood cells.
- High number of platelets in the blood; headache.
A bit frequent (can reach 1 person on 100):
- Severe sudden onset headache - this could be a sign of bleeding in the brain.
- feeling of sensitivity and swelling in the stomach - you may bleed in the stomach.
- Large, irregularly shaped skin lesions with or without blisters

- Skin irritation (local irritation)
 - yellowing of the skin or eyes and your urine becomes darker. It could be a liver problem.
- Rare** (can reach 1 person upon 1 000):
- Severe allergic reaction - signs may include a rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.
- Increased potassium in your blood - this is more likely to happen in people with kidney problems or diabetes. Your doctor can check it by performing a blood test.
- An increase in the number of eosinophil in your blood - your doctor can check this by doing a blood test.
- Hair loss
- Osteoporosis (a condition that makes your bones more susceptible to breakage) 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 anesthesia in the spine
- Difficulty controlling your bladder or bowels (you can't control yourself when you go to the bathroom)
- Hardened lump or lump at the injection site.

TELL YOUR DOCTOR OR PHARMACIST OF ANY UNDESIRED AND INTERESTED EFFECT THAT IS NOT MENTIONED IN THIS LEAFLET.
5. How to store ENOXAMED®:
- Keep out of the reach and sight of children.
- Store it in the primary container of origin, at less than 30°C temperature.
- Do not freeze the pre-filled syringes.

- Do not use ENOXAMED® after the expiry date, which is stated on the pre-filled syringe's label and on the carton's bottom.
 - Do not use ENOXAMED® if you notice particles in the solution or a changing in its color.
 - Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of no longer required medicines. These measures will help in protecting the environment.
- 6. Further information:**
a. What ENOXAMED® contains:
The drug substance is enoxaparin sodium.
The other ingredient is: water for injections.

b. What ENOXAMED® looks like and contents of the pack:
- Pre-filled syringes.
- Limpid solution of yellowish to slightly brownish color.
- Sterile injectable solutions S.C. / Intravascular dosed at:
- 2000 IU anti-Xa (20 mg)/0.2 ml, and at 4000 IU anti-Xa (40 mg)/0.4 ml. Boxes of 2 or 6.
- 6000 IU anti-Xa (60 mg)/0.6 ml and at 8000 IU anti-Xa (80 mg)/0.8 ml. Boxes of 2 or 10.
- 10000 IU anti-Xa (100 mg)/1 ml and. Box of 2.

c. Marketing Authorization Holder and Manufacturer:

UNIMED LABORATORIES
I.Z. Kalaa Kebira - P.O.Box: 38 - 4060 TUNISIA
Phone: (+ 216) 73 342 669 - Fax: (+216) 73 342 472
Web Site: www.unimed.com.tn
d. This leaflet was last approved in {01/2022}; version number {xx}.
e. List I
f. Registration number in Lebanon:
- ENOXAMED® 0.2 ml Box of 2: xxxxxxxx
- ENOXAMED® 0.2 ml Box of 6: xxxxxxxx
- ENOXAMED® 0.4 ml Box of 2: xxxxxxxx
- ENOXAMED® 0.4 ml Box of 6: xxxxxxxx
- ENOXAMED® 0.6 ml Box of 2: xxxxxxxx
- ENOXAMED® 0.6 ml Box of 10: xxxxxxxx
- ENOXAMED® 0.8 ml Box of 2: xxxxxxxx
- ENOXAMED® 0.8 ml Box of 10: xxxxxxxx
- ENOXAMED® 1 ml Box of 2: xxxxxxxx

THIS IS A MEDICINE

- This is a product that affects your health and not following the method of administration puts you at risk.
- Follow carefully the doctor's prescription, the directions for use and the pharmacist's advice.
- The doctor and the pharmacist are the experts on the medicine and know its benefits and risks.
- Do not stop taking the medicine on your own.
- Do not renew the supply of this medicine without consulting the doctor.
- Keep medicines away from children.

COUNCIL OF ARAB HEALTH MINISTERS