

## PATIENT INFORMATION LEAFLET

### SELOPARIN 25 000 IU/5 ml solution for injection.

#### Sterile

#### It is for subcutaneous and intravenous administration.

Each 5 ml vial contains:

- ❖ *Active substance:* 25000 IU heparin sodium
- ❖ *Excipients:* Benzyl alcohol, sodium chloride, water for injections and sodium hydroxide or hydrochloric acid to keep acidity on normal levels.

**Read all of this SELOPARIN carefully before you are given 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for personally; you should not pass it on to others.*
- *During use of this medicine please tell to your doctor that you use this medicine when you go to the doctor or hospital.*
- *Follow the information in the leaflet exactly. Do not use **lower or higher** dosages regarding the medicine.*

#### **In this Patient Information Leaflet:**

- 1. What SELOPARIN is and what is it used for?**
- 2. What you need to know before you use SELOPARIN?**
- 3. How to use SELOPARIN?**
- 4. What are the possible side effects?**
- 5. How to store SELOPARIN?**

**Headings are provided.**

#### **1. What SELOPARIN is and what is it used for?**

SELOPARIN belongs to a group of drugs that are called anticoagulants as heparin sodium. SELOPARIN vial contains heparin sodium in a liquid solution. The box contains one vial. SELOPARIN is standard heparin.

Heparin sodium helps to stop blood clotting. Blood flow is allowed to continue uneventfully.

Blood carrying veins in body are named arteries or veins.

SELOPARIN is used in the following cases:

- To prevent further development of harmful blood clots in veins (arteries or veins) (for treatment)
- To help to stop harmful blood clots in veins (arteries or veins) (preventive)
- Hemodialysis and heart surgery
- If the risk of heart attack or stroke are available
- Several blood coagulation disorders

Blood clots in the body can occur in leg veins (deep vein thrombosis, DVT), in the lungs (pulmonary embolism).

If you have more weight or are pregnant or have some blood diseases or have had DVT or pulmonary embolism. Heart attack, paralysis, long term inactivity can increase clot risk.

## **2. What you need to know before you use SELOPARIN?**

*If you are under epidural and spinal anesthesia;*

*Please tell your doctor, If you are pregnant and/or you have used heparin before taking an anaesthetic.*

*Please inform to person who gives narcosis (dentist included) that you received SELOPARIN in case of planned operation.*

Health personnel will make regular checks after taken anesthesia. It will be checked whether purpleness and bleeding around spine.

These problems can cause irreversible paralysis. This situation can occur like tremble (shiver) on legs or body, weakness or numbness, back pain or urinary problem. But they are seen very rarely.

Your doctor will tell you when you can take medicine after anesthesia

### **YOU SHOULD NOT BE GIVEN SELOPARIN if you:**

- have hypersensitivity to heparin sodium or any of the ingredients of SELOPARIN (Benzyl alcohol)
- have or have ever had thrombocytopenia (a serious blood disorder which prevents blood from clotting properly)
- have hemophilia (a genetic disorder which may cause you to bleed excessively)

- have very high blood pressure
- have serious liver problems
- have peptic ulcer
- have known endocarditic (inflammation of the covering layer of inner surface of the heart and heart valves)
- have ever had bleeding into the brain.
- have injuries in the spine, brain, eyes and ears
- have recently had surgery of the brain, spine eyes or ears or you will have surgery like this.
- have the possibility of miscarriage.

Heparin sodium cannot be given to premature, newborn babies or babies of up to one month.

**TAKE SPECIAL CARE with SELOPARIN if you:**

- suffer from allergies or have previously had an allergic reaction to low molecular weight (LMW) heparin such as Tinzaparin, enoksaparin or deltapirin
- have kidney problems
- have liver problems
- have eye disorders (Retina)
- have blood pressure problems (high pressure)
- suffer from diabetes
- have recently had lumbar puncture
- have metabolic acidosis
- suffer from high levels of potassium in your blood or are taking a medicine that may increase the potassium level in your blood (e.g. amiloride, spironolactone).
- have any condition which makes you to bleed more easily
- will use for 1 to 3 years old children, please tell your doctor
- are taking another medicines affecting blood coagulation at the same time with heparin, please check ‘Application while taking other medicines’ for these medicines list.
- are pregnant or wish to become pregnant.

Please read ‘important informations about excipients contained in SELOPARIN’

Your doctor will do your blood tests before application of Seloparin and during your use. Your doctor can check medicine’s dose. These tests check coagulation cells (thrombocyte) and potassium level of the blood.

This medicine can cause to bleed easily. Your doctor or your nurse should be careful when other injection or operation are applied.

If these warnings are available for any period in the past. Please tell your doctor.

**Administration of SELOPARIN with food and beverages**

Heparin cannot be given if you drink large amounts of alcohol.

## **Pregnancy**

*Please consult your doctor or pharmacist before using this medicine.*

Your doctor can apply heparin during pregnancy, if necessary is. After using heparin, epidural anesthesia especially cannot be applied during birth.

*Please consult your doctor or pharmacist if you notice that you are pregnant during treatment.*

## **Breast-feeding**

*Please consult your doctor or pharmacist before using this medicine.*

It can be used during breastfeeding.

## **Driving and using machines**

SELOPARIN usually can have low effect on driving or using machines. Please consult your doctor if you feel a side effect which retains using car.

## **Important information about some of the excipients in SELOPARIN**

This medicinal product contains 33,21 mg sodium in each 5 ml vial. This situation should be considered if patients are on sodium diet.

SELOPARIN contains benzyl alcohol (9,45mg/ml) as preservative. Please be careful when suspected patients are prescribed for. It cannot be applied for premature and newborn babies.

It may cause allergic reactions and toxic reactions for babies and children up to 3 years old.

If you are pregnant, you doctor will decide to apply Seloparin.

## **Administration while taking other medicines**

- If you use angiotensin converting enzyme inhibitor or enalapril, losartan or valsartan called angiotensin II antagonists for high blood pressure or heart problems treatment, your potassium blood level can increase.(hyperkalemia)
- If you use ibuprofen or diclofenac called non-steroidal anti-inflammatory drugs for arthritis or other pains, possibility of bleeding can be very easily.
- If you use aspirin called drugs of salicylate group to prevent blood clot or to reduce pain or inflammation, possibility of bleeding can be very easily.
- If you use clopidogrel called platelet aggregation inhibitors to stop harmful blood clot, possibility of bleeding can be very easily.
- If you use streptokinase called thrombolytic agents to lyse blood clot, possibility of bleeding is very high level.
- If you use warfarin called vitamin K antagonist to stop harmful blood clot, possibility of bleeding is very high level.
- Glyceryl trinitrate infusion for angina treatment can increase heparin's effect.
- Activated protein C: to get rid of blood clot. Possibility of bleeding can be very easily.
- If you take dextran to increase blood volume, possibility of bleeding can be very easily.

- Corticosteroids (gluco-): excluding hydrocortisone used for replacement therapy in Addison's disease.
- Cephalosporins: Some cephalosporins, e.g. cefaclor, cefixime and ceftriaxone, can affect the coagulation process and may therefore increase the risk of hemorrhage when used concurrently with heparin.
- Tobacco smoke: Nicotine may partially counteract the anticoagulant effect of heparin. Increased heparin dosage may be required in smokers.

If you take above medicines at the same time as heparin, your doctor can do check up tests included blood tests.

*Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including medicines obtained with or without prescription.*

### **3. How to use SELOPARIN?**

#### **Instructions for the appropriate usage and dose / frequency of application:**

Heparin concentration in SELOPARIN is 5 000 IU/ml. All heparin preparations do not contain same concentration. Because of that heparin dose is stated as IU.

SELOPARIN will be applied from doctor or nurse.

Your doctor will decide the dose of medicine given to you depending on your medical condition and will apply to you.

SELOPARIN cannot be injected mixing with another medicines.

#### **Administration route and method of administration:**

SELOPARIN is applied by intravenously or subcutaneous.

#### **Various age groups:**

##### **Children**

SELOPARIN cannot be used for children under one month.

##### **The elderly**

For elderly patients, the dose should be reduced. aPTT (activated partial thromboplastin time) should be followed.

#### **Administration for certain groups**

##### **Renal and Liver failure**

If you have kidney or liver problems. Your doctor can decide to be taken lower dose SELOPARIN.

*Please talk to your doctor or pharmacist if you think that the effect of SELOPARIN is too strong*

*or too weak.*

### **If you think you have been given too much SELOPARIN**

Your doctor or nurse do not apply SELOPARIN at high doses.

If you think that SELOPARIN is given to you at high doses. Please talk your doctor or your nurse.

Hemorrhage (serious bleeding) may occur. (Please look 4. section)

Protamine sulphate can be applied with another injection.

*Please talk to your doctor and pharmacist if you use SELOPARIN more than you need to use.*

### **If you forget to take SELOPARIN**

Your doctor or nurse do not apply SELOPARIN at high doses.

If you forget to take a dose. Please talk your doctor or nurse.

*Please talk to your doctor and pharmacist if you have any questions for implementation of this medicine*

## **4. What are possible side effects?**

Like all medicines, side effects can be seen in people who are sensitive to the ingredients of SELOPARIN.

Please inform your doctor or pharmacist if you have any side effect, worsening of one of the side effects or any side effect that is not mentioned in this leaflet.

**If any of the following cases occurs, discontinue SELOPARIN, IMMEDIATELY inform your physician or admit to the emergency service of the closest hospital:**

- Difficulty breathing
- Swelling of face and throat
- Severe skin rash
- Bubbles around the injection site.

All of these are very serious side effects.

If you have one of these, it means you have a serious allergy against SELOPARIN. You may need urgent medical attention or hospitalization.

**Tell your doctor immediately or refer to the emergency of nearest hospital if you notice any of the following after epidural anesthesia or spinal anesthesia. Paralysis may occur:**

- Tingling ,weakness or numbness (legs or down from the waist)
- Back pain
- Urinary problems.

**Tell your doctor if you notice any of followings. It means serious bleeding:**

- Red or brown urine
- Black feces like tar
- Unusual bruising
- Unceasing bleeding in the nose and mouth or surgical wound

**Other side effects include:**

**Very common side effects (affects 1 user in 10 patients)**

- Injection site reactions: Irritation may occur when injected locally under the skin.

**Common side effects (less than 1 user in 10 patients but more than 1 user in 100 patients)**

- Rash
- Itchy raised rashes (urticaria)
- The reduction of bone density (osteoporosis). Bones of patients treated with heparin for a long time can be broken easily and can be occurred power loss.

**Uncommon side effects (less than 1 user in 100 patients but more than 1 user in 1000 patients)**

- Decreased bone density (osteoporosis). Patients who use heparin for a long time will lose their bones and break easily.
- Hair loss

**Rare side effects (less than 1 user in 10000 patients)**

- Easy bruising or easy bleeding. Harmful blood clot may occur. Cells providing the coagulation (thrombocytes) decrease. Your doctor can explain this situation.
- Changes in the blood test results. Potassium level can increase. If you have serious kidney problems or diabetes, change possibility of the blood test results may be more high. Your doctor can explain this situation.
- Various hypersensitivity symptoms and severe allergic reactions (conjunctivitis, rhinitis, asthma, tachycardia, fever, etc.), anaphylactoid reactions and anaphylactic shock (very serious allergic reactions)
- Increased serum transaminase, gamma-GT, LDH and lipase values (some enzymes that can be measured by blood tests) may occur; but usually resolve on discontinuation of heparin. If you are unsure, ask your doctor.
- Bleeding can occur. Especially too much heparin can cause bleeding.
- Necrosis of skin may occur. If this occurs treatment should be discontinued immediately.

**Very rare (< 1/1000 but ≥1/10.000)**

- Long time painful erections in men

- Anaphylactoid reactions and anaphylactic shock (very severe allergic reactions)

*Please talk to your doctor if you think that any of the above side effects may occur. Some side effects can be serious.*

*Please inform your doctor or pharmacist, if you notice any side effects not listed in this leaflet.*

### **Reporting of the side effects**

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine

### **5. How to store SELOPARIN?**

*Keep SELOPARIN out of the reach and sight of children. Keep SELOPARIN in the package.*

Keep at room temperature below 25° C. Protect from freezing.

Chemical and physical in use stability has been demonstrated for 28 days at 25°C

Please be careful that solution is clear and has unopened packaging before application.

Multidose vial is for use of one patient.

### **Use in accordance with expiration dates.**

*Do not use after the expiry date on the packaging of SELOPARIN. Do not use SELOPARIN if you notice any damage at the packaging.*

### ***Marketing Authorization Holder:***

Haver Farma İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1  
Beykoz / ISTANBUL / TURKEY

### ***Manufacturing Site(s):***

Haver Trakya İlaç San. ve Tic. A.Ş.  
Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB  
Ergene/TEKİRDAĞ/ Turkey

*This patient information leaflet is approved at 21.10.2020*