

## PATIENT INFORMATION LEAFLET

### TRANEXEL 250 mg/2.5 mL I.V. Solution for Injection

Sterile

Administered intravenously.

- **Active substance:** One ampoule contains 250 mg tranexamic acid.
- **Excipient:** Water for injection

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.**

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell to your doctor that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

#### **What is in this Leaflet:**

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

**Headings are included.**

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

- TRANEXEL box contains 10 ampoules of 2.5 mL containing tranexamic acid for injection.
- TRANEXEL is in the group of drugs that facilitate clot formation called antifibrinolytic.
- It can be used to stop excessive bleeding after surgery or to facilitate coagulation. When bleeding occurs in any part of our body, blood clotting is tried to prevent blood loss. In some people, clots do not develop enough and there may be excessive bleeding.

TRANEXEL is used in the following situations:

- It is used in the treatment of severe bleeding in various surgeries (gynecological, urological, general surgery).

- It can be used in the treatment of primary menorrhagia, intrauterine device (IUD) application or bleeding during pregnancy.
- It can be given in addition to the treatment for bleeding in the stomach and duodenum.
- It can be used in hemorrhages seen in liver cirrhosis and cancers, and heavy bleeding due to lung damage.
- It can be used for long-term prophylactic therapy in patients with hereditary angioneurotic edema.
- It can be used for treatment of bleeding that develops in hemophilia patients with an inherited coagulation disorder.
- It can be used to stop bleeding in the anterior chamber of the eye (hyphema).
- Can be applied to eliminate the effects of fibrin-dissolving drugs and to stop bleeding due to these drugs.
- Also; It can be used in cases of diffuse intravascular coagulation (a fatal disease characterized by diffuse hemorrhages) where fibrin dissolution system activity is dominant.

## **2. What you need to know before you use TRANEXEL**

### **DO NOT USE TRANEXEL in the following cases;**

- Do not use this medicine if you are allergic (hypersensitive) to the active substance (tranexamic acid) in its content of TRANEXEL (tranexamic acid) or any substance from its other components.
- In patients with acquired color vision disorders,
- In severe kidney failure due to the risk of accumulation in the body,
- Intracranial bleeding,
- If you have ever had a problem with clot development in your legs or lungs,
- If you have a diffuse intravascular coagulation disorder dominated by the coagulation system.
- TRANEXEL cannot be administered to you if you have a history of convulsions (seizures).

Tranexamic acid has intravenous and oral forms and should not be administered except for the recommended route of administration (intrathecal and intraventricular injection, intracerebral) due to the risk of brain edema and seizures.

### **USE TRANEXEL CAREFULLY for the following cases;**

- If your vision is disturbed during TRANEXEL treatment,
- If you have kidney disease, you may need to use lower doses as the drug can build up in your body.

- If there is blood in your urine (Especially in hemophilia patients, urinary tract obstruction may develop when TRANEXEL is used for bleeding in the upper part of the urinary tract.)
  - Be careful if you have uncontrolled bleeding.
  - If you have extensive intravascular coagulation, your physician will perform a series of blood tests to see if TRANEXEL treatment is right for you.
  - If you are taking birth control medication; Be careful when using TRANEXEL as it may increase the risk of blood clotting,
  - If you are going to use TRANEXEL for a long time, your doctor will ask you to have regular eye tests and liver function tests.
  - Obese, smoking women over 35 years of age using a birth control method (containing hormones) should use this medicinal product with caution because it carries a risk of clot development.
- If these warnings are valid for you, even at any time in the past, please consult your doctor.

### **Use of TRANEXEL with food and drink**

TRANEXEL can be administered on an empty or full stomach.

### **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

Your doctor will guide you about the use of TRANEXEL during pregnancy.

*If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

TRANEXEL passes into breast milk in very low amounts. Your doctor will guide you about its use during breastfeeding.

### **Driving and using machines**

There is no information on this subject. Consult your doctor if you think that the drug has a negative impact on your driving and using machines.

### **Important information about some excipients found in the composition of TRANEXEL**

If you do not have any hypersensitivity to the substances contained in TRANEXEL, no negative effects are expected due to these excipients.

### **Use with other medicines**

When TRANEXEL is used together with drugs that prevent clot development (oral anticoagulants,

heparin), clot dissolving drugs (fibrinolytics) and aspirin, its effect may decrease.

If you are given blood or a liquid containing penicillin, TRANEXEL should not be added to them.

Since administration of TRANEXEL increases the risk of clots in women using hormonal birth control methods, it should not be used together with it.

*If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.*

### **3. How to use TRANEXEL**

#### **Instructions for appropriate use and dose/administration frequency:**

The dose of TRANEXEL required for you will be calculated by your doctor according to your needs. Usually 5-10 mL is administered 3 times a day. In cases where the treatment period exceeds 3 days, your doctor may recommend that you start the oral form of this drug.

#### **Method of administration:**

TRANEXEL can be administered slowly (1 mL in 1 minute) or it can be administered drop by drop by diluting.

TRANEXEL can be mixed with isotonic sodium chloride, isotonic glucose, 20% fructose, dextran 40, dextran 70 and ringer solution.

#### **Various age groups**

##### **Pediatric Use:**

The dose to be administered in children will be calculated based on the child's weight.

##### **Geriatric Use:**

If there is no kidney disorder, there is no need to change the dose.

#### **Special use cases:**

##### **Renal impairment:**

If you have kidney failure, your doctor will make dose adjustments.

##### **Hepatic impairment:**

There is no need for dose adjustment in liver failure.

*Talk to your doctor or pharmacist if you have the impression that the effect of TRANEXEL is too strong or weak.*

**If you have used more TRANEXEL than you should**

No problem with overdose has been reported with TRANEXEL to date.

Headache, dizziness, nausea, vomiting, diarrhea and low blood pressure may occur.

*If you have used TRANEXEL more than you should, talk to a doctor or pharmacist.*

**If you forget to use TRANEXEL**

Your doctor will decide when to administer the missed dose.

It is important to follow your doctor's instructions for the new administration time of the following dose.

*Do not administer a double dose to make up for forgotten doses.*

**Effects that may occur when treatment with TRANEXEL is concluded**

No adverse effects are expected when treatment with TRANEXEL is concluded.

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

Like all medicines, there may be side effects in people who are sensitive to the substances contained in TRANEXEL.

**If any of the following occur, stop using TRANEXEL and IMMEDIATELY inform your doctor or go to the nearest emergency department:**

- Hypersensitivity symptoms such as difficulty in breathing, tightness in the throat, sudden rash on the face should be considered as an allergic reaction.
- If you experience pain, swelling and redness in your legs or chest pain, difficulty in breathing, this may be due to the development of clots in the veins of your legs or lungs.
- Paralysis symptoms such as walking, speech disorders and sensory loss may develop. This may be due to a blockage in the brain vessels.
- If symptoms such as vision loss and color vision deterioration develop, your eye vessels may be blocked.

These are all very serious side effects.

If you have one of these, you may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

**If you notice any of the following, immediately report to your doctor or contact the emergency department of your nearest hospital:**

- Fall in blood pressure and associated dizziness (usually during rapid intravenous administration).

- Difficulty in urinating (usually more common in hemophilia patients with heavy urinary bleeding and may develop due to obstruction of the urinary tract).
- Dizziness.
- Development of convulsions (seizures), especially as a result of misuse.

All these are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.

**If you notice any of the following, tell your doctor:**

- Digestive complaints such as nausea, vomiting, diarrhea (usually resolves when the dose is reduced).

These are the mild side effects of TRANEXEL.

Side effects are listed as shown in the categories below:

Very common: Occurs in at least one in 10 patients.

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.

Rare: Less than one in 1,000 patients.

Very rare: Less than one in 10,000 patients.

Unknown: Cannot be estimated based on available data.

**Rare:**

- Digestive complaints such as nausea, vomiting, diarrhea (usually resolves with dose reduction).

**Unknown:**

- Decrease in blood pressure and associated dizziness (usually develops during rapid intravenous administration).
- Difficulty urinating (usually more common in patients with hemophilia who have heavy bleeding in their urine and may develop due to obstruction of the urinary tract).
- Dizziness.
- Development of convulsions (seizures), especially as a result of misuse.

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

### Reporting of 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. By reporting side effects, you will contribute to obtaining more information about the safety of the drug that you are using.

### **5. How to store TRANEXEL**

*Keep TRANEXEL out of the sight and reach of children, and in its packaging.*

Store at room temperature below 25 °C

It should be used immediately after opening. After reconstitution, it is stable for 24 hours at 2-8 °C.

**Use in compliance with the expiry date.**

*Do not use TRANEXEL after the expiration date stated on the packaging.*

Do not throw expired or unused medicines in the garbage! Give them to the collection system designated by the Ministry of Environment, Urbanization and Climate Change.

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

HAYER FARMA İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No: 52/2/1  
Beykoz / İSTANBUL

### ***Manufacturing Site:***

OSEL İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Caddesi No:52  
Beykoz/İSTANBUL

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