

## Tranexamic 100 mg/ml, solution for injection

Tranexamic acid

### What is tranexamic acid 100 mg/ml and what is it used for?

- This medicine contains tranexamic acid, which belongs to a group of medicines called antihemorrhagics, antifibrinolytics, or amino acids.
- This medicine is used in adults and in children over one year of age for the prevention and treatment of bleeding caused by a process that inhibits blood clotting, called "fibrinolysis."
- Specific indications include:
- Heavy menstrual bleeding in women
- Gastrointestinal bleeding
- Urinary tract disorders with bleeding, after prostate surgery or surgical procedures affecting the urinary tract
- Throat, nose, or ear surgeries
- Heart, abdominal, or gynecological surgeries
- Bleeding after treatment with a medicine to dissolve blood clots

When should you not use this medicine or take extra precautions?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine.
- You currently have a condition that leads to blood clots.
- You have a condition called "disseminated intravascular coagulation" where blood starts to clot throughout the body.
- You have kidney problems.
- You have a history of seizures.
- Due to the risk of cerebral edema and seizures, intrathecal (in the spinal cord) and intraventricular (in the cerebrospinal fluid) injection, as well as intracerebral (in the brain) administration, are not recommended.
- If you think any of the above conditions apply to you or if you are unsure, contact your doctor before using this medicine.

### When should you take extra precautions with this medicine?

Contact your doctor before receiving this medicine if any of the following conditions apply to you; it will help them decide if this medicine is suitable for you:

- If you have had blood in your urine, as the use of this medicine may lead to obstruction of the urinary tract.
- If you are at risk of blood clots.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation).
- This medicine may not be suitable for you unless you have acute severe bleeding and blood tests have shown that the process that inhibits blood clotting, called fibrinolysis, is activated.
- If you have had seizures, this medicine should not be administered. Your doctor should use the lowest possible dose to prevent seizures after treatment with this medicine.
- If you are being treated with this medicine for a prolonged period.

Potential disturbances in color vision should be monitored, and if necessary, treatment should be discontinued. Regular eye examinations (including visual acuity, color vision, fundus, visual field, etc.) are recommended during prolonged continuous use of this medicine. In the case of pathological changes in the eyes, especially retinal disorders, your doctor, in consultation with a specialist, should make a decision regarding the need for prolonged use of this medicine.

### Are you taking any other medicines?

If you are taking or have recently taken any other medicines, including Tranexamic Acid 100 mg/ml, or if there is a possibility of using other medicines in the near future, please inform your doctor or pharmacist.

### You should specifically inform your doctor if you are taking the following medications:

- Other medications that help blood clot (antifibrinolytics)
- Medications that prevent blood clotting (thrombolytics)
- Oral contraceptives
- Pregnancy and breastfeeding:
- If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, please consult your doctor before using this medication. Tranexamic acid is excreted in breast milk, so the use of this medication during the breastfeeding period is not recommended.

**Driving and using machinery:** No studies have been conducted on the effects of this medication on driving ability and the ability to operate machinery.

### How to use this medication?

This medication is administered to you via a slow injection into a vein.

**Use in adults:** Your doctor will determine the appropriate dose for you and how long you should use it.

**Use in the elderly:** No dosage reduction is necessary unless there are indications of kidney failure.

**Use in children and adolescents up to 18 years of age:** If this medication is administered to a child (from one year of age), the dose is based on the child's weight. Your doctor will determine the appropriate dose and duration of treatment for the child.

**Use in patients with renal insufficiency:** If you have a kidney problem, your dose of tranexamic acid will be reduced based on a blood test (serum creatinine concentration).

**Use in patients with liver insufficiency:** No dosage reduction is necessary.

**Method of administration:**

- This medication should only be administered slowly into a vein.
- This medication should not be injected into a muscle.

**If more than the recommended dose has been administered:** If more of this medication has been administered than the recommended dose, your blood pressure may temporarily decrease. Consult a doctor or pharmacist immediately.

**Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been observed with this medicine.

Common (may occur in less than 1 in 10 users): Effects on the stomach and intestines: nausea, vomiting, diarrhea.

Uncommon (may occur in less than 1 in 100 users):

**How to store this medicine?**

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box and ampoule after "Exp.:". The expiry date refers to the last day of that month.
- There are no special storage conditions for this medicine.
- Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to dispose of medications that are no longer needed. These measures will help to protect the environment.