Package leaflet: Information for the patient
Tranexamic acid 100 mg/ml Solution for Injection
tranexamic acid

Read all of this leaflet 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, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Tranexamic acid is and what it is used for

Tranexamic acid Injection contains tranexamic acid which belongs to a group of medicines called antihaemorragics; antifibrinolitics, amino acids
Tranexamic acid Injection is used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

Specific indications include:
- Heavy periods in women
- Gastrointestinal bleeding
- Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear, nose or throat surgery
- heart, abdominal or gynecological surgery
- bleeding after you have been treated with another medicine to break down blood clots.

2. What you need to know before you are given Tranexamic acid

Do not take Tranexamic acid Injection if you:
- are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- currently have a disease leading to blood clots
- have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot
- have a history of convulsions

Due to the risk of seizures and brain swelling, tranexamic acid must not be given into the spine, epidurally (around the spinal cord) or into the brain.

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before taking Tranexamic acid Injection.

Warnings and precautions

This medicine is ONLY to be given to you through a vein by intravenous injection (IV push). This medicine must not be given into the spine, epidurally (around the spinal cord) or into the brain. Serious harms have been reported when this medicine was given into the spine (intrathecal use). If you notice any pain in your back or legs during, or soon after this medicine is given, tell your doctor or nurse immediately.

Tell your doctor if any of these apply to you to help him or her decide if Tranexamic acid Injection is suitable for you:

• If you have had blood in your urine, it may lead to urinary tract obstruction.
• If you have a risk of having blood clots. The risk for blood clotting events may be increased in patients using contraceptives containing hormones.
• If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation) as Tranexamic acid may not be right for you, except if you have acute severe bleeding and blood test have shown the process that inhibits blood clotting called fibrinolysis is activated.
• If you have had convulsions, Tranexamic acid Injection should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Tranexamic acid Injection.
• If you are on a long-term treatment with Tranexamic acid Injection, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of Tranexamic acid regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of Tranexamic acid in your case.

Other medicines and Tranexamic acid Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should specifically tell your doctor if you take or use:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- any contraception containing hormones

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tranexamic acid is excreted in human milk. Therefore, the use of Tranexamic acid Injection during breast-feeding is not recommended.

If you are a woman of child-bearing age, ask your doctor or pharmacist to ensure you are using effective contraception.

Driving and using machines
No studies have been performed on the ability to drive and use machines.

3. How to use Tranexamic acid

Use in adults

Your doctor, nurse or other healthcare provider will give you Tranexamic acid through a slow injection into one of your veins. Do not inject Tranexamic acid yourself. Your doctor will decide the correct dose for you and how long you should take it. You should continue to receive Tranexamic acid for as long as instructed by your doctor.

Consult with your healthcare provider if you have any questions regarding Tranexamic acid.

Use in children
If Tranexamic acid Solution for Injection is given to a child from one year, the dose will be based on the child's weight.
Your doctor will decide the correct dose for the child and how long he/she should take it.

Use in elderly
No reduction in dosage is necessary unless there is evidence of renal failure.

Use in patients with kidney problem
If you have a kidney problem, your dose of tranexamic acid will be reduced according to a test performed on your blood (serum creatinine level).

Use in patients with hepatic impairment
No reduction in dosage is necessary.

Method of administration
Tranexamic acid Injection should only be administered slowly into a vein. Tranexamic acid Injection must not be injected into a muscle, into the spine, epidurally (around the spinal cord) or into the brain

If you are given more Tranexamic acid Injection than the recommended dose
If you are given more Tranexamic acid Injection than the recommended dose you may experience a transitory blood pressure lowering. Talk to a doctor or pharmacist immediately.

4. Possible side effects

Like all medicines this medicine can cause side effects although not everybody gets them.

Side effects reported with Tranexamic acid Injection are:
The following side effects have been observed with Tranexamic acid Injection:

Common (may affect up to 1 in 10 people)
- effects on the stomach and intestines: nausea, vomiting, diarrhoea

Uncommon (may affect up to 1 in 100 people)
- effects on the skin problems: rash

Not known (frequency cannot be estimated from the available data)
- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly
- blood clots
- effects on the nervous system: convulsions
- effects on the eyes: vision disturbances, including impaired colour vision
- effects on the immune system: allergic reactions
- sudden onset kidney problems due to death of the tissue in the outer part of the kidney (acute renal cortical necrosis)

- an allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tranexamic acid

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage condition. Do not use this medicine after the expiry date which is stated on the carton and ampoule label after Exp. The expiry date refers to the last day of that month. Your doctor or nurse will check this before the injection is given.

The unopened ampoules have no special storage precautions.

6. Contents of the pack and other information

What Tranexamic acid Injection contains
The active substance is tranexamic acid.
Each 5 ml of the solution contains 500 mg of tranexamic acid.
Each 10 ml of the solution contains 1000 mg of tranexamic acid.
The other ingredient is water for injections.

What Tranexamic acid Injection looks like and contents of the pack
Tranexamic acid solution for injection is a clear colourless solution, free from visible particulate matter.

Type I glass ampoules are packed in a tray pack or blister pack and further it is packed in a cardboard carton.

Pack sizes
1 x 5 ml
5 x 5 ml
10 x 5 ml
1 x 10 ml
5 x 10 ml
10 x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd,
Euro House,

Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer
Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the member state	Name of the medicine
Czech Republic	Tranexamic acid Accord 100 mg/ml injekční roztok
Estonia	Tranexamic acid Accord
Finland	Tranexamic acid Accord 100 mg/ml injektioneste, liuos
Ireland	Tranexamic acid 100 mg/ml Solution for Injection
Poland	Tranexamic acid Accord
The Netherlands	Tranexaminezuur Accord 100 mg/ml oplossing voor injectie
Norway	Traneksamsyre Accord
Portugal	Tranexamic acid Accord
Sweden	Tranexamic acid Accord 100 mg/ml Injektionsvätska, lösning
United Kingdom (Northern Ireland)	Tranexamic acid 100 mg/ml Solution for Injection

The leaflet was last revised in March 2026

Technical Leaflet intended for healthcare professionals only

Tranexamic acid 100mg/ml Solution for Injection

GENERAL INFORMATION
Tranexamic acid 100mg/ml Solution for Injection is for single use only. Any portion of the vial not used at once should be discarded.

THERAPEUTIC INDICATIONS
Prophylaxis/treatment of haemorrhage due to general or local fibrinolysis in adults and children over one year due to:
- Menorrhagia and metrorrhagia;
- Gastrointestinal bleeding;
- Haemorrhagic urinary disorders, following prostate surgery or procedures on the urinary tract;
- Ear, nose and throat surgery;
- Gynaecological or obstetric surgery;
- Thoracic and abdominal surgery;

- Haemorrhagic complications in association with thrombolytic therapy.

POSOLOGY AND METHOD OF ADMINISTRATION
Tranexamic acid 100mg/ml Solution for Injection should be administered by slow intravenous injection according to the dosage schedule below.

THERAPEUTIC DOSE

Adult:
Local Fibrinolysis: 5-10ml (500-1000mg) by slow intravenous injection (1ml/min), two to three times a day.
General Fibrinolysis:
10ml (1000mg) by slow intravenous injection (1ml/min), every 6 to 8 hours, equivalent to 15mg/kg body weight.

Paediatrics:
From one year, for the current approved indications, the dosage is in the region of 20mg/kg/day.

Elderly:
No reduction in dosage is necessary unless there is evidence of renal failure.

Renal Failure:
Due to the risk of accumulation, the dose should be reduced according to the following table:

Serum Creatinine	Dose iv	Dose Frequency
120–249mcmol/l	10mg/kg BW	every 12 hours
250-500mcmol/l	10mg/kg BW	every 24 hours
>500mcmol/l	5mg/kg BW	every 24 hours

Method of administration:
Slow intravenous injection only.

Tranexamic acid should only be administered intravenously and should not be administered intrathecally or epidural.

In order to reduce the risk of fatal medication errors due to incorrect route of administration of tranexamic acid, it is strongly recommended to label the syringes containing tranexamic acid.

STORAGE AND DISPOSAL OF TRANEXAMIC ACID SOLUTION FOR INJECTION
This medicinal product does not require any special storage condition.
The product should be used immediately after opening. Any unused product or waste material should be disposed of in accordance with local requirements.

Shelf life:
Unopened: 24 months