

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 Injection is and what it is used for
2. What you need to know before you are given Tranexamic acid Injection
3. How to take Tranexamic acid Injection
4. Possible side effects
5. How to store Tranexamic acid Injection
6. Contents of the pack and other information

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

Tranexamic acid Injection contains tranexamic acid which belongs to a group of medicines called antihaemorrhagics; antifibrinolytics.

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 gynaecological 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 Injection

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)
- have (or ever have had) a disease that leads to blood clots
- have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot
- have kidney problems
- have a history of convulsions

Due to the risk of cerebral oedema and convulsions, intrathecal and intraventricular injection and intracerebral application are not recommended.

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

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 blood in your urine, it may lead to urinary tract obstruction.
- If you have a risk of having blood clots.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation) as Tranexamic acid may not be right for you.
- 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.

Other medicines and Tranexamic acid Injection

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins, minerals, herbal medicines or dietary supplements.

You should specifically tell your doctor if you take:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

Pregnancy and breast-feeding

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.

Driving and using machines

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

3. How to take Tranexamic acid Injection

Use in adults

- Treatment of Local Fibrinolysis:
The usual dose is 500-1000mg (5-10ml) two to three times a day.
- Treatment of General Fibrinolysis:
The usual dose is 1000mg (10ml) every 6 to 8 hours, or up to 15mg per Kg of body weight.

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 kidney problems, your dose may be reduced. Your doctor will decide what dose to give you based on a blood test.

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.

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 (you may feel faint or dizzy on standing). 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:

If you experience any of the following side effects after you have been given your medicine, tell your doctor immediately. If you are not in hospital, you **MUST GO** straight away. These side effects are rare but serious.

These side effects are rare but serious.

- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.
- Symptoms of a blood clot which may include swelling or pain in your legs or chest, headache, weakness of the face and limbs on one side of the body.

Other side effects which may occur:

Common (may affect up to 1 in 10 people)

- nausea
- vomiting
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- rash

Not known (frequency cannot be estimated from the available data)

- malaise with hypotension (low blood pressure), especially if the injection is given too quickly
- convulsions
- vision disturbances, including impaired colour vision

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance

Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tranexamic acid Injection

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 medicinal product is authorised in the Member States of the EEA under the following names:

Country	Invented Name
Austria	Tranexamsäure Accord 100 mg/ml Injektionslösung
Belgium	Tranexamic acid Accord 100 mg/ml oplossing voor injectie / solution injectable / injektionslösung
Cyprus	Tranexamic acid Accord 100 mg/ml solution for injection
Czech Republic	Tranexamic acid Accord 100 mg/ml injekční roztok
Germany	Tranexamsäure Accord 100 mg/ml Injektionslösung
Denmark	Tranexamsyre Accord
Estonia	Tranexamic acid Accord
Finland	Tranexamic acid Accord 100 mg/ml injektioneste, liuos
Ireland	Tranexamic acid 100 mg/ml Solution for Injection
Iceland	Tranexamic acid Accord 100 mg/ml, stungulyf, lausn
Italy	Acido Tranexamico Accord
Malta	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	Tranexamic acid 100 mg/ml Solution for Injection
Spain	Tranexamic acid Accord 100 mg/ml, solución inyectable

The leaflet was last approved in 06/2022

Technical Leaflet intended for healthcare professionals only

Tranexamic acid 100mg/ml Solution for Injection

GENERAL INFORMATION

Tranexamic acid 100 mg/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:

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

Method of administration:

Slow intravenous injection only.

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