

Package leaflet: Information for the user

Tranexamic acid 100mg/mL solution for injection/infusion tranexamic acid

Read all of this leaflet carefully before you start taking 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 pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Tranexamic acid injection/infusion contains tranexamic acid which belongs to a group of medicines called antihemorrhagics; antifibrinolytics, aminoacids.

Tranexamic acid 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 use Tranexamic acid

Do not use Tranexamic acid:

- If you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- If you have currently a disease leading to blood clots
- If you have a condition called ‘consumption coagulopathy’ where blood in the whole body starts to clot
- If you have kidney problems
- If you 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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse if any of these apply to you to help him or her decide if Tranexamic acid 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.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), this medicine may not be right for you, except if you have acute severe bleeding and blood tests have shown the process that inhibits blood clotting called fibrinolysis is activated.
- If you have had convulsions, Tranexamic acid should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Tranexamic acid.
- If you are on a long-term treatment with this medicine, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of this medicine, 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 this medicine in your case.

Other medicines and Tranexamic acid

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

You should specifically tell them if you take:

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

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 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 use Tranexamic acid

Tranexamic acid solution for injection/infusion will be given to you by slow injection or infusion into a vein.

Your doctor will decide the correct dose for you and how long you should take it.

Use in children

If this medicine 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 should only be administered slowly into a vein.

Tranexamic acid must not be injected into a muscle.

If you use more Tranexamic acid than the recommended dose

If you are given more Tranexamic acid 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 are:

The following side effects have been observed with Tranexamic acid

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

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 any side effects directly to the national reporting system directly via (see details below) By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: <http://www.mhra.gov.uk/yellowcard>

www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the

Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Tranexamic acid

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

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP.

The expiry date refers to the last day of that month.

Do not freeze.

After first opening: the solution for injection/infusion is for single use only. Unused solution for injection/infusion must be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8° C, unless dilution has taken place in controlled and validated aseptic conditions.

6. Contents of the pack and other information

What Tranexamic acid injection/infusion contains

The active substance is tranexamic acid.

Each mL contains 100 mg of tranexamic acid

Each vial of 5 mL contains 500 mg of tranexamic acid.

Each vial of 10 mL contains 1000 mg of tranexamic acid.

The other ingredient is water for injections.

What Tranexamic acid solution for injection/infusion looks like and contents of the pack

Tranexamic acid is solution for injection/infusion.

Clear, colorless and essentially free from visible particles.

6 mL Type I glass vial containing 5 mL fill volume in blister and cardboard box.

10 mL Type I glass vial containing 10 mL fill volume in blister and cardboard box.

Pack sizes

5 x 5 mL, 10 x 5 mL,

5 x 10 mL, 10 x 10 mL.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ireland:

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht, Netherlands

United Kingdom:

Baxter Healthcare Limited

Caxton Way

Thetford, Norfolk IP24 3SE, United Kingdom

Manufacturer

UAB Norameda
Meistrų g. 8a, Vilniaus m, Vilniaus m.sav., LT-02189, Lithuania.

Bieffe Medital S.p.A.,
Via Nuova Provinciale, 23034 Grossotto (SO) Italy.

Tramco Sp. Z.o.o,
Wolskie, ul. Wolska 14, 05-860 Plochocin, Poland.

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

Austria	Tranexamsäure Baxter 100 mg/ml Injektionslösung/Infusionslösung
Belgium	Tranexamic acid Baxter 100 mg/ml solution injectable/ pour perfusion
Denmark	Tranexamic acid Baxter 100 mg/ml injektions-/infusionsvæske, opløsning
Estonia	Tranexamic acid Baxter
Finland	Tranexamic acid Baxter 100 mg/ml injektio-/infusioneste, liuos
Greece	Tranexamic acid Baxter 100 mg/διάλυμα για ένεση/έγχυση
Germany	Tranexamsäure Baxter 100 mg/ml Injektionslösung/Infusionslösung
Hungary	TRANEXÁMSAV BAXTER 100 mg/m oldatos injekció
Ireland	Tranexamic acid 100 mg/ml solution for injection/infusion
Italy	Acido Tranexamico Baxter 100 mg/ml soluzione iniettabile/infusione
Latvia	Tranexamic acid Baxter 100 mg/ml šķīdums injekcijām/infūzijām
Lithuania	Tranexamic acid Baxter 100mg/ml injekcinis tirpalas
Netherlands	Tranexaminezuur Baxter 100 mg/ml, oplossing voor injectie/infusie
Norway	Tranexamic acid Baxter
Poland	Tranexamic acid Baxter
Portugal	Ácido Tranexâmico Baxter
Slovakia	Tranexamic acid Baxter 100 mg/ml injekčný roztok
Spain	Ácido tranexámico Baxter 100 mg/ml solución inyectable y para perfusión EFG
Sweden	Tranexamic acid Baxter 100 mg/ml solution for injection/infusion
United Kingdom	Tranexamic acid 100 mg/ml solution for injection/infusion

This Leaflet was last revised in April 2022