Package leaflet: Information for the patient

Tranexamic Acid 100 mg/ml, Solution for Injection/Infusion
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. See section 4.

What is in this leaflet

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

Tranexamic Acid Solution for Injection/Infusion contains tranexamic acid which belongs to a group of medicines called 'anti-haemorrhagics' or 'anti-fibrinolytics'.

Tranexamic Acid is used in adults and children above one year of age for the prevention and treatment of bleeding which is caused by a process that inhibits blood clotting called fibrinolysis.

Specific indications include:
- heavy periods in women
- gastrointestinal bleeding
- haemorrhagic urinary disorders, after having an operation on your prostate gland or urinary tract
- after having an operation on your ear, nose or throat
- after having heart, abdominal or gynaecological surgery
- bleeding after you have been treated with another medicine to treat blood clots

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

Do not take Tranexamic Acid if you:
- are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- currently have a blood clot(s) or have every had a disease leading to blood clots. (If you are at risk of having blood clots, see 'Warnings and precautions' below)
- have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot
- have kidney problems
- have a history of convulsions (fits)

Due to the risk of fits or swelling in the brain, injection into the spinal cord, or directly into the heart or into the brain, is not recommended.

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

Warnings and precautions

Tell your doctor if any of these apply to you to help him/her decide if Tranexamic Acid is suitable for you:
- if you have had **blood in your urine**, which could indicate that there is a clot in your upper urinary tract
- if you are **at risk** of having **blood clots** (e.g. family history of blood clots)
- if you suffer from excessive clotting or bleeding throughout your body (disseminated intravascular coagulation). Your doctor may carry out a **blood test** to see if the process that inhibits blood clotting (called 'fibrinolysis') is activated
- if you have had convulsions (**fits**) in the past, as Tranexamic acid should not be used. If you do not have a history of convulsions, your doctor will use the minimum possible dose to avoid convulsions occurring after treatment
- if you are on long-term treatment with Tranexamic Acid, pay attention to any possible disturbances in your colour vision. If necessary, your doctor may discontinue the treatment. With continuous long-term use of Tranexamic Acid, **regular eye tests** are recommended. If changes are seen in your eyes, your doctor may consult an eye specialist in order to decide whether to continue your treatment.

Other medicines and Tranexamic Acid
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should specifically tell your doctor if you take:
- other medicines that help blood to clot called 'anti-fibrinolytic medicines'
- medicines that prevent blood clotting, called 'thrombolytic medicines'
- oral contraceptives

Pregnancy and breast-feeding
Ask your doctor for advice if you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby.

Tranexamic acid is excreted in breast 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.

Tranexamic Acid solution for Injection/Infusion contains less than 1mmol sodium (23mg) per dose, that is to say essentially "sodium-free".

3. How to take Tranexamic Acid

This medicine will be given to you by slow injection or infusion into a vein. It should not be injected into a muscle.
Your doctor will decide the correct dose for you and how long you should take it.

Use in adults
- Treatment of Local Fibrinolysis:
  The usual dose is 500-1000mg (5-10ml) 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
Your doctor will decide the correct dose for the child and how long he/she should take it.
If this medicine is given to a child from the age of one, the dose will be based on the child's weight.

Use in elderly
No reduction in dosage is necessary unless you have kidney problems.

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 liver problems
No reduction in dosage is necessary.

If you are given too much Tranexamic Acid
If you are given too much Tranexamic Acid you may experience temporary low blood pressure (you may feel faint or dizzy on standing). Talk to your doctor or nurse immediately.

4. 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 Tranexamic Acid:

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.

- **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)
- feeling sick
- being sick
- diarrhoea

Uncommon (may affect up to 1 in 100 people)
- rash

Not known (frequency cannot be estimated from the available data)
- low blood pressure (you may feel generally unwell, faint or dizzy on standing) which is usually caused by an injection being given too quickly
- fits
- visual disturbances, including colour disturbance.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
UK: the Yellow Card Scheme at 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tranexamic Acid

This medicine will be stored by your doctor, nurse or pharmacist out of the sight and reach of children.
Do not refrigerate or freeze.
This medicine should not be used 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.

This product is for single use only. Once your doctor or nurse has opened the ampoule, it should be used immediately. Any remaining solution for injection must be thrown away by the doctor or nurse.

6. Contents of the pack and other information

What Tranexamic Acid contains
The active substance is tranexamic acid.
Each ml of the solution contains 100 mg of tranexamic acid.
Each 5 ml ampoule contains 500 mg of tranexamic acid.
Each 10 ml ampoule contains 1 g of tranexamic acid.
The other ingredients are water for injections, sodium hydroxide and hydrochloric acid.

What Tranexamic Acid looks like and contents of the pack
Your medicine is a solution for injection/infusion in a glass ampoule. It is available in cardboard cartons of 1, 5, 10, 20 or 50 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Ibigen S.r.l.
Via Fossignano, 2
04011 – Aprilia (LT)
Italy

Manufacturer:
Labiana Pharmaceuticals, S.L.U, C/Casanova, 27-31 08757 – Corbera del Llobregat – Barcelona, Spain

This leaflet was last revised in 12/2019.

The following information is intended for Healthcare Professionals only

Posology

Adults
Unless otherwise prescribed, the following doses are recommended:
1. Standard treatment of local fibrinolysis:
   0.5 g to 1 g by slow intravenous injection (= 1 ml/minute) two to three times daily
2. Standard treatment of general fibrinolysis:
   1 g by slow intravenous injection (= 1 ml/minute) every 6 to 8 hours, equivalent to 15 mg/kg BW

Patients with renal impairment
In renal insufficiency leading to a risk of accumulation, the use of tranexamic acid is contraindicated in patients with severe renal impairment. For patients with mild to moderate renal impairment, the dosage of tranexamic acid should be reduced according to the serum creatinine level:

Serum creatinine		Dose IV	Administration
µmol/l	mg/10 ml		
120 to 249	1.35 to 2.82	10 mg/kg BW	Every 12 hours
250 to 500	2.82 to 5.65	10 mg/kg BW	Every 24 hours
> 500	> 5.65	5 mg/kg BW	Every 24 hours

Patients with hepatic impairment
No dose adjustment is required in patients with hepatic impairment.

Paediatric Population:
In children from 1 year, the dosage is in the region of 20 mg/kg/day. However, data on efficacy, posology and safety for these indications are limited.

The efficacy, posology and safety of tranexamic acid in children undergoing cardiac surgery have not been fully established.

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

Method of administration
The administration is strictly limited to slow intravenous injection or infusion of maximum 1ml per minute.

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