Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Package leaflet: Information for the user

Tranexamic acid 100 mg/ml solution for injection

tranexamic acid

Read all of this leaflet carefully before you are giventhis 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 contains the active substance tranexamic acid which belongs to a group of medicines called antihaemorragics; antifibrinolitics, aminoacids.
This medicine 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

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)
- if you currently have 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 medicne.

Warnings and precautions
Talk to your doctor or nurse before taking Tranexamic acid if you have any of the following conditions. This will help them decide if this medicine 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, this medicine should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with this medicine.
- 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 of this medicine in your case.

Other medicines and Tranexamic acid:
Tell your doctor, nurse or pharmacist if you are taking or 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 thrombotlytic 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 this medicine 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

This medicine will be given to you by slow injection 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.

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Dosage in adults
Unless otherwise prescribed, the following doses are recommended:

1. Standard treatment of local fibrinolysis:
   0.5 g (1 ampoule of 5 ml) to 1 g (1 ampoule of 10 ml or 2 ampoules of 5 ml) tranexamic acid by slow intravenous injection (= 1 ml/minute) two to three times daily
2. Standard treatment of general fibrinolysis:
   1 g (1 ampoule of 10 ml or 2 ampoules of 5 ml) tranexamic acid by slow intravenous injection (= 1 ml/minute) every 6 to 8 hours, equivalent to 15 mg/kg BW

Use in children

If Tranexamic acid 100 mg/ml solution for injection is given to a child from one year, the dose will be based on the child's weight. The doctor will decide the correct dose for the child and how long he/she should use it.

In children from 1 year, for current approved indications, the dosage is in the region of 20 mg/kg/day.

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

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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
This medicine should only be administrated slowly into a vein.
It must not be injected into a muscle.

If you are given 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.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

Side effects reported with this medicine are:
The following side effects have been observed with this medicine
Common:may affect up to 1 in 10 people
- effects on the stomach and intestines: nausea, vomiting, diarrhoea

Uncommon:may affect up to1 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), 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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month. Your pharmacist will check this before the injection is given.

This medicinal product does not require any special storage conditions

Once opened: Use immediately. Discard any unused portion

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

6. Contents of the pack and other information

What Tranexamic acid contains
- The active substance is tranexamic acid.
  Each ml of solution contains 100 mg of tranexamic acid.
  Each 5 ml ampoule of solution contains 500 mg of tranexamic acid.
  Each 10 ml ampoule of solution contains 1000 mg of tranexamic acid.

The other ingredient is water for injections.

What Tranexamic acid looks like and contents of the pack
Solution for injection.

Type-I clear glass ampoule containing either 5 ml and 10 ml of injection solution. For ease of breaking, the ampoules may bear a “One-Point cut (OPC)” or may be “Scored”. Ampoules are placed in a pre-printed carton.

Pack sizes:
5 ml fill: 1, 5, 6, 10 and 100 Ampoules in a carton
10 ml fill: 5 and 10 Ampoules in a carton

Not all pack sizes may be marketed.

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

Serum creatinine		Dose intravenous	Administration
micromole/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

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

Method of administration
Tranexamic acid 100 mg/ml solution for injection is only to be injected slowly (= 1 ml/minute) into a vein.
Tranexamic acid 100 mg/ml solution for injection must not be injected into a muscle.

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