

# **Package leaflet: information for the Patient**

## **Tranexamic Acid 500mg/5ml Solution for Injection**

**Read all of this leaflet carefully before you, or your child, 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 Solution for Injection is and what it is used for
2. What you need to know before you are given Tranexamic Acid Solution for Injection
3. How Tranexamic Acid Solution for Injection is given
4. Possible side effects
5. How to store Tranexamic Acid Solution for Injection
6. Contents of the pack and other information

### **1. What Tranexamic Acid Solution for Injection is and what it is used for**

Tranexamic Acid 500mg/5ml Solution for Injection (called Tranexamic Acid Solution for Injection throughout the rest of this leaflet) contains tranexamic acid which belongs to a group of medicines called antihæmorrhagics; 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 uses include:

- heavy periods in women;
- gastrointestinal bleeding;
- hæmorrhagic 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 break down blood clots.

### **2. What you need to know before you are given Tranexamic Acid Solution for Injection**

#### **Do not have Tranexamic Acid Solution for Injection if you:**

- are allergic (hypersensitive) to tranexamic acid or any of the other ingredients of this medicine (see section 6, **Further information**);
- currently have or have ever had a disease leading 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 (fits).

Due to the risk of fits or swelling in the brain, injection into the spinal cord, 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 Solution for Injection.

### **Warnings and precautions**

Tell your doctor if any of the following apply to you, to help him or her decide if Tranexamic Acid Solution for Injection 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;
- if you suffer from excessive clotting or bleeding throughout your body (disseminated intravascular coagulation). Your doctor will 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). Your doctor will use the minimum dose possible to avoid further convulsions after the treatment.
- If you are on long term treatment with Tranexamic Acid Solution for Injection 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 Solution for Injection 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 Solution for Injection**

Please tell your doctor or nurse if you are taking, or have recently taken, or might take 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 antifibrinolytic medicines;
- Medicines that prevent blood clotting, called thrombolytic medicines;
- Oral contraceptives.

### **Pregnancy, breast-feeding and fertility**

- Ask your doctor for advice if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.
- Tranexamic acid is excreted in breast milk. Therefore, the use of Tranexamic Acid Solution for 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 Tranexamic Acid Solution for Injection is given**

Tranexamic Acid Solution for Injection will be given to you by a slow injection into your vein.

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. This will usually be given by a slow injection into your vein.
- 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**

- The doctor will decide the right dose to give your child and how long he or she should take it.
- If Tranexamic Acid Solution for Injection is given to a child over one year old, the dose will be based on the child's body weight.

### **Use in Elderly**

No reduction in dose is necessary unless you have kidney problems.

### **Use in Patients with Kidney Problems**

If you have problems with your kidneys, the 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 dose is necessary.

### **Method of Administration**

Tranexamic Acid Solution for Injection should only be injected slowly into a vein. It should not be injected into a muscle.

### **If you are given too much Tranexamic Acid Solution for Injection**

If you are given too much Tranexamic Acid Solution for Injection, 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.

**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 users)**

- feeling sick;
- being sick;
- diarrhoea.

**Uncommon (may affect up to 1 in 1000 users)**

- rash.

**Not known (the 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.

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 nurse.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Section, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto: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 Solution for Injection**

Do not store above 25°C. Store in the original packaging. Do not refrigerate or freeze.

Tranexamic Acid Solution for Injection will be stored by your doctor, nurse or pharmacist, out of the sight and reach of children.

Tranexamic Acid Solution for Injection should not be used after the expiry date stated on the carton and vial label. The expiry date refers to the last day of that month.

This product is for single use only. Once your doctor or nurse has opened the vial, it should be used immediately. Any remaining Tranexamic Acid Solution for Injection must be thrown away by the doctor or nurse.

**6. Contents of the pack and other information**

**What Tranexamic Acid Solution for Injection contains**

- The active substance is tranexamic acid. Each 5ml vial contains 500mg tranexamic acid (100mg per ml).
- The other ingredient is water for injections.

**What Tranexamic Acid Solution for Injection looks like and contents of the pack**

This medicine is a clear, colourless solution in a clear, glass vial. Each vial contains 5ml of medicine. This product is available in cartons containing 10 x 5ml vials.

**Marketing Authorisation Holder**

Focus Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

Tel: 00 44 1283 495 280

Fax: 00 44 1283 495 290

Email: [medinfo@focuspharma.co.uk](mailto:medinfo@focuspharma.co.uk)

**Manufacturer**

Medochemie Ltd, Ampoule Injectable Facility, 48 Iapetou Street, Avios Athanasios Industrial estate, 4101, Limassol, Cyprus.

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

**Other sources of information**

**For information in large print, audio CD or Braille please telephone 00 44 (0)1283 495 280 or email [medinfo@focuspharma.co.uk](mailto:medinfo@focuspharma.co.uk).**

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**Technical Leaflet intended for healthcare professionals only**

**TRANEXAMIC 500MG/5ML SOLUTION FOR INJECTION**

**GENERAL INFORMATION**

Tranexamic Acid 500mg/5ml 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 500mg/5ml 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), 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>
120–249mcmol/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.

Each ampoule may contain more than the stated 5ml of liquid. This is to ensure that the full 5ml amount is available. Only 5ml should be withdrawn from the ampoule for administration to the patient. Any portion of the ampoule not used at once should be discarded.

**STORAGE AND DISPOSAL OF TRANEXAMIC ACID SOLUTION FOR INJECTION**

Do not store above 25°C. Store in the original packaging. Do not refrigerate or freeze.

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: 30 months