

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tranexamic Acid 500 mg film-coated tablets

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4

What is in this leaflet:

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

1. WHAT TRANEXAMIC ACID TABLETS IS AND WHAT THEY ARE USED FOR

Tranexamic Acid belongs to a group of medicines called anti-fibrinolytic drugs. These are used to stop or reduce unwanted bleeding. When you bleed your body forms clots to stop the bleeding. In some people these break down causing too much bleeding. Tranexamic Acid stops these clots dissolving and so reduces unwanted bleeding.

Tranexamic Acid is used to prevent or reduce bleeding for a short period of time in many different conditions. You may have been prescribed it for one of the following:

- Following prostate surgery (post-prostatectomy)
- Following bladder surgery
- Heavy periods (menorrhagia)
- Nose bleeds (epistaxis)
- Cervical surgery (conisation of the cervix)
- Bleeding inside the eye (traumatic hyphema)
- Tooth removal (dental extraction) in haemophiliacs (people who bleed more easily than normal). You will know if this refers to you
- A hereditary disease called angioneurotic oedema (HANO). A doctor will have told you if you have this.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRANEXAMIC ACID

Do not take Tranexamic Acid:

- if you are allergic to tranexamic acid or to any of the other ingredients of this medicine (listed in section 6)
- if you have serious problems with your kidneys (kidney failure)

- if you have a blood clot in your blood vessels (called a `thrombosis`).
- if you have a history of blood clots in your blood vessels (called a `thrombosis`)
- if you have disseminated intravascular coagulation (DIC), a disease where your blood starts to clot throughout your body
- if you have a history of fits

If any of the above applies to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Tranexamic Acid:

- if you have blood in your urine
- if you have ever had any uncontrollable bleeding
- if you have disseminated intravascular coagulation (DIC), a disease where your blood starts to clot throughout your body
- if you have been taking medicine to treat a hereditary disease called angioneurotic oedema (HANO) every day for a long time. If so, you may need to have regular eye tests and blood tests to check your liver is working properly
- if you are a woman with irregular periods
- if you have a history of blood clots in your blood vessels (called a `thrombosis`)
- if anyone in your family has suffered from blood clots in their blood vessels
- if you have kidney disease.
- if you have been taking oral contraceptives

Other medicines and tranexamic acid

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. You should specifically tell your doctor if you take:

- Fibrinolytic drugs (used to help dissolve blood clots), such as streptokinase. This is because Tranexamic Acid will stop these drugs working

Pregnancy and breast-feeding and fertility

If you are pregnant, or breast feeding, think you might be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

3. HOW TO TAKE TRANEXAMIC ACID

Always take this medicine exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember: Your medicine should always be taken with a glass of water. The tablets should be swallowed whole. Do not crush or chew them.

Adults and the elderly:

- The usual dose is 2 or 3 tablets taken two to three times daily

- The exact dose you take will depend on why you have been prescribed these tablets
- Follow your doctor's instructions about how many tablets to take, when to take them and for how long.

Use in children:

- Your doctor will tell you exactly how much medicine you should give your child. They will work out the dose according to how much your child weighs.

Patients with kidney problems:

- Your doctor will tell you how much to take. The dose you take may be lower than the usual adult dose.

If you take more Tranexamic Acid than you should

If you accidentally take too much of your medicine, immediately tell your doctor or go to the nearest hospital casualty department. Taking too much Tranexamic Acid may make you feel sick, be sick or be dizzy or light-headed upon standing.

If you forget to take Tranexamic Acid

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop taking this medicine and go immediately to the hospital if you experience any of the following symptoms

- pain or feeling of heaviness in your chest
- sudden shortness of breath
- coughing up blood
- unusual pain or swelling in your arms or legs
- fainting

You may have developed a blood clot in your legs or lungs

Stop taking you medicine and tell your doctor immediately if experience any of the following rare symptom

- problems with your eyesight, especially your colour vision
- a blood clot in your eye. This may cause bleeding in the eye or loss of vision
- allergic reaction (mild symptoms include itching and/or skin rash: more severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)

Very rare side effects (may affect up to 1 in 10,000 people)

- Feeling sick
- Being sick
- Diarrhoea

If they occur, tell your doctor or pharmacist who may reduce the dose.

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

Do not store above 30 °C. Store in the original package.

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

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Tranexamic Acid contains:

- The active substance is tranexamic acid. Each tablet contains 500 mg tranexamic acid.
- The other ingredients are:
Tablet core: Cellulose microcrystalline, povidone (K 90), croscarmellose sodium, silica colloidal anhydrous, talc, magnesium stearate
Film coating: methacrylate polymers, titanium dioxide (E171), talc, magnesium stearate, macrogl (8000).

What Tranexamic Acid looks like and contents of the pack.

Tranexamic Acid tablets are white to off white, capsule shaped, biconvex film-coated tablets. They are marked with TXA 500 with a break line.

The tablets come in blister packs containing 60 tablets.

Marketing authorisation holder

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