

Package leaflet: Information for the user

Tranexamic Acid 500 mg Tablets

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 effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Tranexamic Acid 500 mg Tablets are and what they are used for

Tranexamic Acid 500 mg Tablets contain the active substance tranexamic acid, which belongs to a group of medicines known as anti-fibrinolytics which 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 500 mg Tablets is used to prevent or reduce bleeding for a short period of time in many different conditions.

You may have been prescribed this medicine for one or more of the following:

- Following prostate surgery (post-prostatectomy) or bladder surgery
- Heavy periods (menorrhagia)
- Nose bleeds (epistaxis)
- Cervical surgery (conisation of the cervix)
- Bleeding inside the eye (traumatic hyphaema)
- Tooth removal (dental extraction) in haemophiliacs (people with inherited blood clotting disorder who bleed more easily). 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 500 mg Tablets

Do not take Tranexamic Acid 500 mg Tablets

- if you are allergic to tranexamic acid or 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 or have ever had a blood clot in your blood vessels (called a 'thrombosis')
- if you have a history of convulsions
- if you are at risk of excessive bleeding as a result of a bleeding disorder called consumption coagulopathy.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Tranexamic Acid 500 mg Tablets if

- you have blood in your urine. This may increase the risk of blockage of the urinary tract.
- you have ever had any uncontrolled bleeding
- you have disseminated intravascular coagulation (DIC), a disease where your blood starts to clot throughout your body
- 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 that your liver is working properly.
- you are a woman with irregular periods
- you or your family have a history of blood clots in your blood vessels (called a 'thrombosis')
- you have kidney disease.

Other medicines and Tranexamic Acid 500 mg Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription.

This is especially important if you are taking the following medicines:

- Fibrinolytic drugs, (used to dissolve blood clots) such as streptokinase. This is because Tranexamic Acid 500 mg Tablets will stop these drugs working.
- Oral contraceptives. These may increase the risk of blood clots forming.

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 for advice before taking this medicine.

Driving and using machines

Tranexamic acid has no or little effect on the ability to drive and use machines. Visual disturbances may occur after taking tranexamic acid.

3. How to take Tranexamic Acid 500 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

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

The breakline is not intended for breaking the tablet.

Use in adults and the elderly

The usual dose is 2 or 3 tablets taken two or 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 and adolescents

- 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.

Use in 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 500 mg Tablets than you should

If you accidentally take too much of your medicine, immediately tell your doctor or go to the nearest hospital casualty department. Take your medicine and this leaflet with you.

Taking too much Tranexamic Acid 500 mg Tablets may cause diarrhoea or make you feel sick, be sick or be dizzy or light-headed upon standing and convulsions (fits).

If you forget to take Tranexamic Acid 500 mg Tablets

Do not take a double dose to make up for a missed 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 seek immediate medical advice if you experience any of the following:

Rare: may affect up to 1 in 1,000 people

- a blood clot in your leg or lungs, the symptoms of which may include:
 - pain, swelling or redness in your leg
 - difficulty breathing or shortness of breath
 - chest pain, which may get worse while breathing

Very rare: may affect up to 1 in 10,000 people

- an allergic reaction, the symptoms of which may include:
 - swelling of your throat and tongue
 - difficulty breathing or shortness of breath
 - difficulty swallowing, tightness in your throat or a hoarse voice
 - wheezing, coughing or noisy breathing
 - a rash that is swollen, raised or itchy

Stop taking this medicine and tell your doctor immediately if you experience any of the following:

Rare: may affect up to 1 in 1,000 people

- itchy, red or swollen skin
- problems with your eyesight, especially your colour vision
- a blood clot in your eye. This may cause bleeding in the eye, or a loss of vision

Very rare: may affect up to 1 in 10,000 people

- a blood clot in your blood vessels (called a 'thrombosis')
- feeling sick, being sick, diarrhoea. These are usually mild and pass very quickly, but if they continue, tell your doctor or pharmacist.

Frequency not known (cannot be estimated from the available data)

- seizures, particularly in cases of misuse
- sudden onset kidney problems due to death of the tissue in the outer part of the kidney (acute renal cortical necrosis).
- an allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 500 mg Tablets

Keep all medicines out of the sight and reach of children.

Do not store above 25°C. Keep in the original package. Do not use this medicine after the expiry date that is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Tranexamic Acid 500 mg Tablets contain

The active substance is tranexamic acid. Each tablet contains 500 mg of tranexamic acid. The other ingredients are: microcrystalline cellulose, povidone K90, croscarmellose sodium, colloidal anhydrous silica, talc, magnesium stearate, methacrylate polymers, titanium dioxide (E171), macrogol 8000 and vanillin.

What Tranexamic Acid 500 mg Tablets look like and the contents of the pack

Tranexamic Acid 500 mg Tablets are film-coated, white to off-white, oblong and biconvex with a breakline and marked "TA" on one side of the breakline.

They are available in blister packs of 12 and 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom.

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

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