

Package leaflet: Information for the user

Tranexamic Acid 500mg 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 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
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 is and what it is used for

Tranexamic Acid 500mg Tablets (hereinafter referred to as Tranexamic Acid) are an antifibrinolytic agent used to reduce bleeding. When you bleed your body forms clots or plugs as part of healing. In some people these plugs do not stay in place long enough. This can cause too much bleeding. Tranexamic acid helps these plugs to stay in place.

Tranexamic acid can be used to prevent or reduce bleeding for a short period of time in many different conditions. You could have been prescribed this medicine for one of the following reasons:

- following prostate surgery
- heavy periods
- nose bleeds
- surgery to the cervix in women
- bleeding inside the eye
- tooth removal in haemophiliacs
- a hereditary disease called angioneurotic oedema (HANO).

2. What you need to know before you take Tranexamic Acid

Do not take Tranexamic Acid if you have or have had:

- an allergic (hypersensitive) reaction to Tranexamic Acid or any of the other ingredients of Tranexamic Acid Tablets (see section 6 for other ingredients)

- a blood clot, for example in your leg or lungs
- kidney failure
- fits
- any condition which has caused you to have a blood clot or means that you are at risk of developing a blood clot.

Warnings and precautions

Tell your doctor before taking Tranexamic Acid if:

- you have blood in your urine. This may increase the risk of blockage of the urinary tract
- you have ever had any uncontrollable bleeding
- you take oral contraceptives. These may increase the risk of blood clots forming
- 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 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')
- anyone in your family has suffered from blood clots in their blood vessels
- you have kidney disease.

Children under 15 years of age with heavy menstrual bleeding should consult their doctor before use.

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 must tell your doctor or pharmacist if you are already taking any of the following medicines:

- fibrinolytics, drugs which help to dissolve blood clots, such as streptokinase
- medicines that may affect the ability of your blood to clot, or that may increase the risk of clots forming, such as oestrogens which may be present in some oral contraceptives and some hormone replacement therapies.

Taking Tranexamic Acid with food and drink

The tablets should be taken with a glass of water.

The tablets should be swallowed whole. Do not crush or chew them.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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. (continued overleaf)

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tranexamic Acid

Always take this medicine exactly as described in this leaflet or as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual adult dose is 2-3 tablets two-three times daily. However, your doctor may have prescribed you a different dose. If you are taking this medicine for heavy periods, do not take more than 4g daily (8 tablets). The dose will be reduced if you have kidney disease.

Children

The child dose is worked out according to the patient's body weight.

Your doctor will tell you how long you will need to take this medicine for, as this will depend on your condition.

If you take more Tranexamic Acid than you should

As with all medicines an overdose of this medicine could be dangerous. If you have taken an overdose tell your doctor or go to the nearest hospital casualty department immediately.

Taking too much Tranexamic Acid may make you feel sick, be sick or be dizzy or lightheaded upon standing.

If you forget to take Tranexamic Acid

If you forget to take your tablets you should take your next dose as usual. Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Tranexamic Acid can cause side effects, although not everybody gets them.

If you experience the following rare side effects stop taking this medicine immediately and speak to your doctor:

- colour vision disturbance
- changes in your eyesight

Rare side effects

- a blood clot in your eye which may cause bleeding in the eye, or a loss of vision
- itchy, red or swollen skin (allergic reaction)

Very rare side effects

- allergic reactions which cause difficulty in breathing or dizziness
- nausea, sickness or diarrhoea. Reducing the dose may prevent these symptoms
- a blood clot in your blood vessels (thrombosis)

Frequency not known

- fits

If any of these 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, 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

Keep medicines out of the sight and reach of children. This product should not be used after the expiry date which appears on the blister strips. Do not store above 25°C.

Store in the original carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Tranexamic Acid contains

Each tablet contains 500mg of tranexamic acid. The tablets also contain calcium hydrogen phosphate anhydrous, croscarmellose sodium, povidone, talc and magnesium stearate.

What Tranexamic Acid looks like and contents of the pack

The tablets are white to off-white and capsule shaped. They are engraved with "TXA 26" on one side, and are plain on the other side.

They are supplied in cartons containing 60 tablets.

Marketing Authorisation Holder:

Manx Healthcare Ltd, Taylor Group House
Wedgnoek Lane, Warwick, CV34 5YA, UK

Manufacturer:

Laboratorios Alcalá Farma S.L.
Avenida de Madrid, 82, Alcalá de Henares,
28802 Madrid, Spain

Other Formats

To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

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