

Package leaflet: Information for the patient

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 effects not listed in this leaflet. See section 4.

In this leaflet:

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1. What Tranexamic acid 500 mg film-coated tablets are and what it is 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 500 mg film-coated tablets are 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 (prevention of recurrent haemorrhage in traumatic hyphaema)
- 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 500 mg film-coated tablets

Do not take Tranexamic acid 500 mg film-coated tablets if

- You are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- You have serious problems with your kidneys (kidney failure)
- You have or have ever had a blood clot in your blood vessels (called a 'thrombosis').
- You have a history of convulsions
- 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 film-coated tablets if:

- You have blood in your urine
- 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.

Other medicines and Tranexamic acid 500 mg film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including medicines obtained without a prescription), in particular the following:

- Fibrinolytic drugs (used to help dissolve blood clots), such as streptokinase. This is because Tranexamic acid 500 mg film-coated tablets will stop these drugs working

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, 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 500 mg film-coated tablets contain castor oil, sodium and propylene glycol

Tranexamic acid 500 mg film-coated tablets contain castor oil. This can cause stomach upset and diarrhoea.

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

This medicine contains 5.50% w/w, propylene glycol as an ingredient necessary for the medicine to work properly.

3. How to take Tranexamic acid 500 mg film-coated 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.

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

Use in 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 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 film-coated 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.

Taking too much Tranexamic acid 500 mg film-coated tablets may make you feel sick, be sick or be dizzy or light-headed upon standing.

If you forget to take Tranexamic acid 500 mg film-coated 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 on 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.

Tell your doctor immediately if you experience any of the following symptoms:

- allergic reactions which cause difficulty in breathing or dizziness
- itchy, red or swollen skin

Rare (affects 1 to 10 users in 1,000)

- 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 (affects less than 1 user in 10,000)

- a blood clot in your blood vessels (called a ‘thrombosis’)
- feeling sick (nausea) or being sick (vomiting). This is usually mild and passes very quickly, but if it continues, tell your doctor or pharmacist
- diarrhoea. This is usually mild and passes very quickly, but if it continues, tell your doctor or pharmacist.

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

- Convulsions, particularly in cases of misuse.

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 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 film-coated tablets

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 after “EXP”. The expiry date refers to the last day of that month.

Use within 25 days after first opening the HDPE bottle.

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 to protect the environment.

6. Contents of the pack and other information

What Tranexamic acid 500 mg film-coated tablets contain

The active substance is Tranexamic acid. Each tablet contains 500 mg Tranexamic acid.

The other ingredients are: cellulose microcrystalline, starch pregelatinised, low substituted hydroxypropyl cellulose, silica colloidal anhydrous, povidone, talc, castor oil hydrogenated, magnesium stearate, hypromellose, titanium dioxide, macrogol, propylene glycol, sodium lauryl sulfate.

What Tranexamic acid 500 mg film-coated tablets looks like and contents of the pack

Tranexamic acid tablets are off white to pale yellow, oval shaped film-coated tablet plain on both sides.

Tranexamic acid 500 mg film-coated tablets are supplied in:
Blister packs (OPA/Alu/PVC) containing 10, 20, 30, 50, 60 and 100 tablets.
HDPE (High density polyethylene) bottles containing 100 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Laboratories Ltd,
220 Butterfield
Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturer¹

Emcure Pharma UK Ltd,
Basepoint Business Centre
110 Butterfield, Great Marlings
Luton, LU2 8DL
United Kingdom

Tillomed Laboratories Ltd
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¹ Only the actual release site will be listed

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