Package leaflet: Information for the user

Tranexamic acid 500 mg film-coated tablets
tranexamic acid

Read all of this leaflet carefully before you start using 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Tranexamic acid 500 mg film-coated tablets are and what it is used for
2. What you need to know before you use Tranexamic acid 500 mg film-coated tablets
3. How to take Tranexamic acid 500 mg film-coated tablets
4. Possible side effects
5. How to store Tranexamic acid 500 mg film-coated tablets
6. Contents of the pack and other information

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)
• Severe Nose bleeds (Severe epistaxis)
• Cervical surgery (conisation of the cervix)
• To prevent repeated bleeding inside the eye (Prevention of recurrent hemorrhage 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 in 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 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

- 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
- Oral contraceptives. These may increase the risk of blood clots forming
- Any other medicine, including medicines obtained without a prescription.

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 Tranexamic acid 500 mg film-coated tablets.

Tranexamic Acid is excreted into breast milk although the amount is minimal. If you are breastfeeding talk to your doctor or pharmacist before taking Tranexamic acid 500 mg film-coated tablets

Tranexamic acid 500 mg film-coated tablets contain castor oil

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

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 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 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
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 get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, stop taking the capsules straight away and tell your doctor immediately
• you have blood clots in the veins (an rare side effect that may affect up to 1 in 1000 people) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately

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
– itchy, red or swollen skin

Very rare (affects less than 1 user in 10,000)
– a blood clot in your blood vessels (called a `thrombosis`).
– allergic reactions which may cause difficulty in breathing or dizziness.
– feeling sick (nausea)
– being sick (vomiting)
– diarrhoea
– fits or seizures (convulsions)
– a general feeling of illness (malaise) with low blood pressure (hypotension) with or without loss of consciousness

Nausea, vomiting and diarrhoea are usually mild and pass very quickly, but if they continue, tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in 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 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 label. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
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.

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

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

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