PHARMACODE

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, Tranexamic acid 500 mg film-coated tablets will be called Tranexamic acid.

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 Film coated Tablets contain the active substance tranexamic acid and belong 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 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

Do not take Tranexamic acid 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 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

Other medicines and Tranexamic acid
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular the following:
- Fibrinolytic drugs (used to help dissolve blood clots), such as streptokinase. This is because Tranexamic acid will stop these drugs working.

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 or pharmacist 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

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 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 cause diarrhoea or make you feel sick, be sick or be dizzy or lightheaded upon standing.

If you forget to take Tranexamic acid
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 Tranexamic acid and go immediately to hospital if you experience any of the following symptoms:

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 Tranexamic acid and tell your doctor immediately if you experience any of the following symptoms:
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 of 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 Website: 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.

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5. How to store Tranexamic acid
Keep this medicine out of the sight and reach of children.

Do not use Tranexamic acid after the expiry date on the carton. The expiry date refers to the last day of that month.

Store in the original package.

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 contains
- The active substance is tranexamic acid.
  Each film-coated tablet contains 500 mg tranexamic acid.

- The other ingredients are:
  Tablet core
  Microcrystalline cellulose, povidone, croscarmellose sodium, colloidal anhydrous silica, talc, magnesium stearate

  Tablet coating
  Methacrylate copolymer, talc, magnesium stearate, polyethylene glycol 8000, isopropyl alcohol.

What Tranexamic acid looks like and contents of the pack
White to off white (approximately 18.1 mm x 8.1 mm) capsule shaped biconvex film coated tablet plain on one side and central break-line on the other side.

Tranexamic acid film coated tablets are available in blister packs of 30 and 60 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Dawa Limited,
5 Sandridge Close,
Harrow, Middlesex,
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Manufacturer
Drugsrus Limited,
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