PACKAGE LEAFLET

Package leaflet: Information for the user

Tranexamic acid 1000 mg coated granules in sachet
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 is used for heavy menstrual bleedings.
Tranexamic acid is a drug that reduces menstrual bleeding. Tranexamic acid 1000 mg coated granules in sachet contains tranexamic acid, which prevents the enzyme which dissolves blood clots to act. This causes less blood loss and quicker cure rate.
Tranexamic acid should only be used when your periods are regular and you are 15 years old and above.

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

Please note that Tranexamic acid should only be used if your periods are regular and heavy. To be sure,
you should answer yes to both the following questions:
1. Are your periods regular, i.e. your menstrual cycle is between 21 to 35 days long?
2. Do you need to use double sanitary protection, towels plus tampons or double towels to prevent bleeding through, alternatively change sanitary protection very often?

Do not take Tranexamic acid
- if you are treated for blood clot e.g in legs, lungs or brain
- if you have severe reduced kidney function
- if you have a history of convulsions (seizures or fits)
- if you are taking a combined hormonal contraceptive (“the pill”, vaginal ring or patch)
- if you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Tranexamic acid if you have any of the followings:
- Your periods are irregular
- You have ever had a blood clot and your parents and/or brothers or sisters have had a blood clot
- You have had blood in your urine in between your periods

- You have reduced kidney function.

If heavy bleeding occurs during use of combined hormonal contraceptives ("the pill", vaginal ring or patch), you should not start tranexamic acid, but consult your Healthcare professionnal.

Heavy menstrual bleedings can occur due to diseases in the womb such as myoma or polyps. If they are taken care of, the heavy menstrual bleeding decreases. If anything is unclear, you should ask your gynaecologist.

Continued gynaecological health controls are recommended.

Children and adolescents
Clinical experience with Tranexamic acid in menorrhagic children under 15 years of age is not available.

Other medicines and Tranexamic acid
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If Tranexamic acid is taken at the same time as anticoagulants, it could potentially affect the way that Tranexamic acid or the anticoagulants work.

Pregnancy and breast-feeding
Tranexamic acid is indicated for regular heavy menstrual bleedings and is not intended for use during pregnancy. Impact of breastfeeding for the child seems unlikely at therapeutic doses. Ask your doctor or pharmacist for advice if you are breastfeeding.

Driving and using machines
Side effects that can affect the ability to drive and use machines have been reported. If you feel dizzy or have problems with your eyesight you should not drive or use machines until the symptoms have passed.

Tranexamic acid 1000 mg coated granules in sachet contains sucrose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Tranexamic acid

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

Coated granules can be swallowed with a glass of water.
Treatment should start when your period has started. The recommended dose for adults and adolescents from 15 years is 1 sachet 3 times daily as long as needed, for a maximum of 4 days. The dosage can be increased to a maximum of 4 sachets per day (1 sachet every 6 to 8 hours), if bleeding remains heavy after starting treatment. Your doctor may prescribe a different dose.
See your doctor if you do not respond to treatment with tranexamic acid.

If you take more Tranexamic acid than you should
If you have taken more Tranexamic acid than you should, or if children have been taking medicine by accident, contact your doctor or hospital to get an opinion of the risk and advice on action to be taken. Signs of an overdose may include dizziness, headache, nausea, diarrhoea, low blood pressure, myopathy and convulsions. It may include increased risk of thrombosis if you are predisposed.

If you forget to take Tranexamic acid

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 patients): Nausea, vomiting, diarrhoea, stomach pain, headache, dizziness. These side effects are often mild and transient.

Uncommon (may affect up to 1 in 100 patients): Allergic skin reactions.

Not known (frequency cannot be estimated from the available data): Rare cases of blood clots, changes in colour vision and other problems with the eyesight, convulsions. 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.

If Tranexamic acid does not have sufficient effect or if you do not tolerate Tranexamic acid , there are other
methods to treat heavy menstrual bleedings. Contact your gynaecologist who can give information about those methods.

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

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.

This medicine does not require any special storage conditions.

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 1000 mg coated granules in sachet contains
- The active substance is tranexamic acid. Each sachet contains 1000 mg of tranexamic acid.
- The other ingredients are: Sugar spheres (sucrose, maize starch), Povidone K30 (E1201), Sucralose (E955), Silica colloidal anhydrous (E551), Polyacrylate dispersion 30 per cent, Talc (E553B) .

What Tranexamic acid 1000 mg coated granules in sachet looks like and contents of the pack
Coated granules in sachet (LDPE / Aluminium / LDPE / Paper).
White to off-white coated granules.
Box of 12 sachets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
CEMAG CARE
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Manufacturer
ATHENA IPS
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