

Package leaflet: Information for the user

Cyklokapron 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, Cyklokapron 500 mg film-coated tablets will be called Cyklokapron.

What is in this leaflet:

1. What Cyklokapron is and what it is used for
2. What you need to know before you take Cyklokapron
3. How to take Cyklokapron
4. Possible side effects
5. How to store Cyklokapron
6. Contents of the pack and other information.

1. What Cyklokapron is and what it is used for

Cyklokapron contains the active substance tranexamic acid and 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. Cyklokapron stops these clots dissolving and so reduces unwanted bleeding.

Cyklokapron 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 Cyklokapron

Do not take Cyklokapron 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 Cyklokapron 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 Cyklokapron

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 Cyklokapron 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.

3. How to take Cyklokapron

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 Cyklokapron 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 Cyklokapron may make you feel sick, be sick or be dizzy or light-headed upon standing.

If you forget to take Cyklokapron

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 Cyklokapron can cause side effects, although not everybody gets them.

Eye disorders

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

Immune system disorders

Very rare (affects less than 1 user in 10,000)

- this includes allergic reactions which cause difficulty in breathing or dizziness.

Vascular disorders

Very rare (affects less than 1 user in 10,000)

- A blood clot in your blood vessels (called a 'thrombosis').

Gastrointestinal disorders

Very rare (affects less than 1 user in 10,000)

- Feeling sick
- Being sick
- Diarrhoea

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

Skin and subcutaneous tissue disorders

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

- Itchy, red or swollen skin

Nervous system disorders

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, 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cyklokapron

Keep this medicine out of the sight and reach of children.

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

Do not store above 25 °C.

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 Cyklokapron contains:

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

- The other ingredients are microcrystalline cellulose (E460), hydroxypropyl cellulose (E463), talc (E553b), magnesium stearate (E572), colloidal anhydrous silica, povidone (E1201), methacrylate polymers, titanium dioxide (E171), polyethylene glycol 8000, vanillin.

What Cyklokapron looks like and contents of the pack

Cyklokapron tablets are white, oblong film-coated tablets. They are marked with CY with an arc above and below the lettering.

The tablets come in plastic bottles containing 50 tablets or in blister packs containing 60 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder

Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers

Madaus GmbH, Lütticher Str. 5, 53842 Troisdorf, Germany

This leaflet was last revised in February 2023.

If this leaflet is difficult to see or read, or you would like it in a different format, please contact Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom