

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.

The name of your medicine is Cyklokapron 500 mg film-coated tablets, which will be called Cyklokapron tablets throughout this leaflet.

What is in this leaflet:

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

1. What Cyklokapron Tablets are and what they are used for

Cyklokapron tablets contain the active ingredient tranexamic acid, which belongs to a group of medicines called antifibrinolytic drugs.

Cyklokapron tablets are used for the short-term treatment or prevention of haemorrhage (severe bleeding) for the following conditions:

- Prostatectomy (removal of part or all of the prostate gland)
- Bladder surgery
- Menorrhagia (a heavy and prolonged period in women)
- Epistaxis (nosebleed)
- Conisation of the cervix (removal of part of the cervix to help diagnosis)
- Traumatic hyphaema (bleeding behind the eye caused by injury)

Cyklokapron tablets are also used:

- Treatment of hereditary angioneurotic oedema (an inherited condition causing swelling of the face and hands)
- To prevent severe bleeding after tooth extraction in haemophiliacs (people with a bleeding disorder)
- To treat severe bleeding of the upper digestive tract.

2. What you need to know before you take Cyklokapron tablets

Do not take Cyklokapron tablets:

- If you have or have had a history of blood clots in your arteries or veins (such as ‘deep vein thrombosis’)
- If you have had bleeding in the brain.
- If you have serious problems with your kidneys (severe kidney disease).
- If you have a history of convulsion (seizures or fits).
- If you are at risk of excessive bleeding as a result of a bleeding disorder called consumption coagulopathy (causes severe bleeding or bruising).
- If you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cyklokapron tablets if you have any of the following conditions:

- Kidney disease (a reduction in dosage is recommended)
- Large amounts of blood in your urine especially if you have haemophilia (a condition which prevents your blood from clotting)
- You have intravascular coagulation, a disease where your blood starts to clot
- You have irregular menstrual bleeding (periods) of unknown cause.
- You or your family have a history of blood clots in your blood vessels (called a 'thrombosis')
- You have a history of convulsions

Other medicines and Cyklokapron tablets

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

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Cyklokapron tablets:

- Fibrinolytic drugs (drugs that break down blood clots such as streptokinase or urokinase)
- Oral Contraceptives (this may result in an increased risk of thrombosis).
- Any other medicine, including medicines obtained without a prescription.

It may still be all right for you to be given Cyklokapron tablets and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

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, who will decide whether or not you should be given Cyklokapron tablets. A small amount of Cyklokapron is found in breast milk. If you want to breast-feed, you should inform your doctor.

Driving and using machines

There are no known affects on driving or operating machinery.

3. How to take Cyklokapron 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.

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

The dose depends on the condition being treated and the weight of the person. Your doctor will calculate the correct dose for you.

Adults and the elderly: The recommended dose is 15-25 mg/kg bodyweight (2-3 tablets), 2-3 times daily.

- Prostatectomy: the treatment should be started with Cyklokapron Injection; thereafter 2 tablets (1.0g) 3-4 times daily.
- Menorrhagia: 2-3 tablets (1.0-1.5g) 3-4 times daily for 3-4 days.
- Epistaxis: 2 (1.0g) tablets 3 times daily should be administered for 7 days.
- Conisation of the cervix: 3 (1.5g) tablets 3 times daily.
- Traumatic hyphaema: 2-3 tablets (1.0-1.5g) 3 times a day.
- Hereditary angioneurotic oedema: 2-3 tablets 2-3 times daily intermittently for some days, or continuously.
- Haemophilia: In the management of dental extractions 2-3 (1.0-1.5g) tablets every eight hours.
- Upper gastrointestinal haemorrhage: the treatment should be started with Cyklokapron Injection every 6 hours for the first 3 days, then 2-3 (1.0-1.5g) tablets orally every 6 hours for a further 3-4 days. Patients with kidney disease require a lower dose, which will be calculated by your doctor.

Children: The dose is calculated according to body weight at 20 mg/kg/dose.

If you take more Cyklokapron tablets than you should

Contact your doctor immediately or go to the nearest hospital casualty department. Signs of overdose may be feeling sick, vomiting, or dizziness when standing up.

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Common: may affect up to 1 in 10 people

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)

– Allergic reactions including those which cause difficulty in breathing or dizziness

Cardiovascular disorders

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

– Low blood pressure which may make you feel unwell or lose consciousness

Vascular disorders

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

– Blocking of a blood vessel by a blood clot (called a ‘thromboembolic event’)

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

– A blood clot in your arteries or veins (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.

Nervous system disorders

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

– Convulsions, particularly in the case of misuse

Skin and subcutaneous tissue disorders

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

– Itchy, red or swollen skin or venous thrombosis at any sites if you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 HPRAs Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cyklokapron 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 original container after “EXP”.

The expiry date refers to the last day of that month. Store below 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 tablets contain:

Each tablet contains 500 mg of the active ingredient tranexamic acid.

The other ingredients are:

Tablet Core: microcrystalline cellulose (E460), hypolose (E463), talc (E553b), magnesium stearate (E572), silica anhydrous, colloidal povidone (E1201)

Film-coating: methacrylate copolymers (Eudragit E100), titanium dioxide (E171), Macrogol 8000, vanillin, talc (E553b), magnesium stearate (E572).

What Cyklokapron tablets look like and contents of the pack

Cyklokapron tablets are white, capsule-shaped, with the letters CY on one side and scored on the other side.

Cyklokapron tablets are available in white, plastic containers with screw caps containing 50 tablets or blister strips of 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatrix Healthcare Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, Dublin, Ireland

Manufacturers

Madaus GmbH, 51101 Cologne, Germany

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