

Package leaflet: Information for the user

Cyklokapron® 100 mg/mL solution for injection/infusion tranexamic acid

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cyklokapron is and what it is used for
2. What you need to know before you are given 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 tranexamic acid which belongs to a group of medicines called antihaemorrhagics; antifibrinolytics, amino acids.

Cyklokapron is used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

Specific indications include:

- Heavy periods in women
- Gastrointestinal bleeding
- Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear, nose, or throat surgery
- Heart, abdominal, or gynecological surgery
- Bleeding after you have been treated with another medicine to break down blood clots.

2. What you need to know before you are given 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).
- If you currently have a disease leading to blood clots.
- If you have a condition called ‘consumption coagulopathy’ where blood in the whole body starts to clot.
- If you have a history of convulsions.

Due to the risk of seizures and brain swelling, Cyklokapron must not be given into the spine, epidurally (around the spinal cord) or into the brain.

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before taking Cyklokapron.

Warnings and precautions

This medicine is ONLY to be given to you through a vein either by intravenous infusion (IV) or intravenous injection (IV push). This medicine must not be given into the spine, epidurally (around the spinal cord) or into the brain. Serious harms have been reported when this medicine was given into the spine (intrathecal use). If you notice any pain in your back or legs during, or soon after this medicine is given, tell your doctor or nurse immediately.

Tell your doctor if any of these apply to you to help him or her decide if Cyklokapron is suitable for you:

- If you have had blood in your urine, it may lead to urinary tract obstruction.
- If you have a risk of having blood clots. The risk for blood clotting events may be increased in patients using contraceptives containing hormones.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), Cyklokapron may not be right for you, except if you have acute severe bleeding and blood test have shown the process that inhibits blood clotting called fibrinolysis is activated.
- If you have had convulsions, Cyklokapron should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Cyklokapron.
- If you are on a long-term treatment with Cyklokapron, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of Cyklokapron, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of Cyklokapron in your case.

Other medicines and Cyklokapron

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

You should specifically tell your doctor if you take or use:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- any contraception containing hormones

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.

Tranexamic acid is excreted in human milk. Therefore, the use of Cyklokapron during breast-feeding is not recommended.

If you are a woman of child-bearing age, ask your doctor or pharmacist to ensure you are using effective contraception.

Driving and using machines

No studies have been performed on the ability to drive and use machines.

3. How to use Cyklokapron

Your doctor, nurse or other healthcare provider will give you Cyklokapron through a slow injection or infusion into one of your veins. Do not inject Cyklokapron yourself. Your doctor will decide the correct dose for you and how long you should take it. You should continue to receive Cyklokapron for as long as instructed by your doctor.

Consult with your healthcare provider if you have any questions regarding Cyklokapron.

Use in children

If Cyklokapron is given to a child from one year, the dose will be based on the child's weight. Your doctor will decide the correct dose for the child and how long he/she should take it.

Use in elderly

No reduction in dosage is necessary unless there is evidence of renal failure.

Use in patients with kidney problem

If you have a kidney problem, your dose of tranexamic acid will be reduced according to a test performed on your blood (serum creatinine level).

Use in patients with hepatic impairment

No reduction in dosage is necessary.

Method of administration

Cyklokapron should only be administered slowly into a vein.
Cyklokapron must not be injected into a muscle or into the spine.

If you are given more Cyklokapron than the recommended dose

If you are given more Cyklokapron than the recommended dose you may experience a transitory blood pressure lowering. Talk to a doctor or pharmacist immediately.

4. Possible side effects

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

Side effects reported with Cyklokapron are:

The following side effects have been observed with Cyklokapron

Common (may affect up to 1 in 10 people)

- effects on the stomach and intestines: nausea, vomiting, diarrhoea

Uncommon (may affect up to 1 in 100 people)

- effects on the skin problems: rash

Not known (frequency cannot be estimated from the available data)

- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly
- blood clots
- effects on the nervous system: convulsions
- effects on the eyes: vision disturbances including impaired colour vision
- effects on the immune system: allergic reactions

Reporting of suspected adverse reactions

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 HPRÁ 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

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 and ampoule label after EXP. The expiry date refers to the last day of that month.

Do not freeze.

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 in Cyklokapron 100 mg/mL solution for injection/infusion is tranexamic acid. The other ingredient is water for injections.

What Cyklokapron looks like and contents of the pack

Cyklokapron 100 mg/mL solution for injection/infusion: Type I glass ampoule containing a clear, colourless solution.

Packs with 5 or 10 Type I glass 5 mL ampoules, each ampoule in an outer carton containing 500 mg tranexamic acid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road
Dublin 4
D04 K7N3
Ireland

Manufacturer

Pfizer Manufacturing Belgium NV
Rijksweg 12
B-2870 Puurs-Sint-Amands
Belgium

Company contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4,
D04 K7N3, Ireland
Telephone 1-800 633 363

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Germany, Ireland, Netherlands, Norway, Sweden, United Kingdom (Northern Ireland):
Cyklokapron
Denmark, Iceland: Tranexamsyre Pfizer
United Kingdom (Northern Ireland): Tranexamic acid Pfizer

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