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Package leaflet: Information for the user

Cyklokapron® 100 mg/mL

solution for injection/infusion

tranexamic acid

PAA141260
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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

Cyklokapron contains tranexamic acid which belongs to a group of medicines called antihaemorragics; antifibrinolitics, aminoacids.
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 kidney problems.
- If you have a history of convulsions.

Due to the risk of cerebral oedema and convulsions, intrathecal and intraventricular injection and intracerebral application are not recommended.

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
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.
- 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:
- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

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

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

3. How to use Cyklokapron

Cyklokapron will be given to you by slow injection or infusion into a vein.
Your doctor will decide the correct dose for you and how long you should take it.

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.

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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 administrated slowly into a vein.
Cyklokapron must not be injected into a muscle.

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.

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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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@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, 6 or 10 Type I glass 5 mL ampoules in an outer carton, each ampoule containing 500 mg tranexamic acid.

Packs with 10 x 1 Type I glass 5 mL ampoules in an outer carton, each ampoule containing 500 mg tranexamic acid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Pfizer Healthcare Ireland,
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Manufacturer:
Pfizer Manufacturing Belgium
Rijksweg 12
B-2870 PUURS
BELGIUM

Company contact address:
For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland
Telephone 1-800 633 363

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Luxemburg, Estonia, Germany, Ireland, Netherlands, Norway, Sweden, United Kingdom: Cyklokapron
Denmark, Iceland: Tranexamsyre Pfizer
United Kingdom: Tranexamic acid Pfizer

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