Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package leaflet: Information for the patient
Tranexamic Acid Injection I.P 100 mg/mL
CYKLOKAPRON®

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CYKLOKAPRON (Tranexamic Acid) is and what it is used for

CYKLOKAPRON (Tranexamic Acid) contains tranexamic acid which belongs to a group of medicines called antihaemorrhagics, antifibrinolytics, aminoacids.

CYKLOKAPRON (Tranexamic Acid) is used in adults for the treatment or prevention of bleeding due to a process that inhibits blood clotting called fibrinolysis or fibrinogenolysis.

2. What you need to know before you use CYKLOKAPRON (Tranexamic Acid)

Do not use CYKLOKAPRON (Tranexamic Acid)
- If you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6).
- If you have currently 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 seizures, brain swelling and death, CYKLOKAPRON (Tranexamic Acid) 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 (Tranexamic Acid).

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 (Tranexamic Acid) 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 (Tranexamic Acid) 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 (Tranexamic Acid) should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with CYKLOKAPRON (Tranexamic Acid).
- If you are on a long-term treatment with CYKLOKAPRON (Tranexamic Acid), 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 (Tranexamic Acid), 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 (Tranexamic Acid) in your case.

Other medicines and CYKLOKAPRON (Tranexamic Acid)
Tell your doctor 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 for advice before taking this medicine.

Tranexamic Acid is excreted in human milk. Therefore, the use of CYKLOKAPRON (Tranexamic Acid) 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 (Tranexamic Acid)

CYKLOKAPRON (Tranexamic Acid) will be given to you by slow injection or infusion only into a vein and should not be given by any other routes.

Your doctor will decide the correct dose for you and how long you 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 CYKLOKAPRON (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 (Tranexamic Acid) should only be administrated slowly into a vein.

CYKLOKAPRON (Tranexamic Acid) must not be injected into a muscle, into the spine, epidurally (around the spinal cord) or into the brain.

If you are given more CYKLOKAPRON (Tranexamic Acid) than the recommended dose
If you are given more CYKLOKAPRON (Tranexamic Acid) than the recommended dose you may experience a transitory blood pressure lowering. Talk to a doctor immediately.

4. Possible side effects

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

The following side effects have been observed with CYKLOKAPRON (Tranexamic Acid):

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 color vision.
- Effects on the immune system: Allergic reactions.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

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

5. How to store CYKLOKAPRON (Tranexamic Acid)

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

Store below 30°C. Protect from light. Do not freeze.

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.

6. Contents of the pack and other information

What CYKLOKAPRON (Tranexamic Acid) contains
The active substance in CYKLOKAPRON (Tranexamic Acid) 100 mg/mL solution for injection/infusion is tranexamic acid.

The other ingredient is water for injections.

What CYKLOKAPRON (Tranexamic Acid) looks like and contents of the pack
CYKLOKAPRON (Tranexamic Acid) 100 mg/mL is a clear, colourless solution for injection/infusion.

Each glass ampoule contains 5 mL of Tranexamic Acid solution (100 mg/mL) for injection/infusion.

Manufactured by:
M/s. Pfizer Manufacturing Belgium NV Rijksweg 12, B-2870 Puurs, NA (Belgium).

This leaflet was prepared based on LPD no. LPDTRX072024.