

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**CYKLOKAPRON**[®]

Tranexamic Acid Tablets

Tranexamic Acid Injection

Read this carefully before you start taking **CYKLOKAPRON** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CYKLOKAPRON**.

What is CYKLOKAPRON used for?

CYKLOKAPRON is used in adults and children:

- to treat a genetic disorder known as hereditary angioneurotic edema. This disorder is characterized by severe swelling of tissue under the skin; and
- to prevent or reduce bleeding from cervical cone surgery, tooth extraction, nosebleeds, and bleeding inside the eye.

CYKLOKAPRON can also be used to prevent or reduce bleeding in adults with heavy menstrual periods.

How does CYKLOKAPRON work?

CYKLOKAPRON belongs to a group of medicines called antifibrinolytic agents. It works by blocking the breakdown of blood clots, which helps to prevent or reduce bleeding.

What are the ingredients in CYKLOKAPRON?

Medicinal ingredient: Tranexamic acid.

Non-medicinal ingredients:

- **Tablet:** Cellulose microcrystalline, colloidal silica anhydrous, eudragit E, hydroxypropylcellulose, magnesium stearate, PEG 8000, Povidone, talcum, titanium dioxide, and vanillin.
- **Solution for Injection:** Water for injection.

CYKLOKAPRON comes in the following dosage forms:

Tablet: 500 mg of tranexamic acid.

Solution for injection: 100 mg/mL of tranexamic acid.

Do not use CYKLOKAPRON if:

- you have a history or are at a higher risk for thrombosis (blood clots in the veins or arteries). This includes diseases where a blood clot breaks loose and blocks another blood vessel (e.g., deep vein thrombosis, pulmonary embolism, and cerebral thrombosis).
- you are allergic to tranexamic acid or to any other ingredients in CYKLOKAPRON.
- you have a colour vision problem that is not genetic.
- you have blood in the urine.
- you have bleeding in the space between your brain and the surrounding membrane (subarachnoid haemorrhage).

The CYKLOKAPRON solution for injection is only for intravenous use. Do not administer CYKLOKAPRON

solution for injection using other routes of administration as this can cause serious adverse events including death.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CYKLOKAPRON. Talk about any health conditions or problems you may have, including if you:

- have kidney problems.
- have irregular menstrual bleeding where the cause is not known.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. CYKLOKAPRON can pass into breast milk and affect your unborn baby.
- are taking any of the following:
 - anticoagulants (used to prevent blood clots and thin the blood);
 - hormonal birth control methods (e.g., “the pill”); or
 - tamoxifen (used to treat breast cancer).
- have a condition known as disseminated intravascular coagulation (DIC; excessive blood clotting). CYKLOKAPRON will only be given if your healthcare professional has done blood tests to check that you are suitable, otherwise other anti-clotting medicines may be a better option for you.
- are obese.
- have diabetes.
- have polycystic ovary syndrome (a condition that produces high levels of a male hormone called androgen causing irregular or no periods).
- have a history of cancer of the uterine (endometrial cancer) in a close relative.
- are on estrogen therapy.
- are over the age of 65 years old.
- are at a higher risk for blood clots in the veins or arteries (e.g., a history of blood clots or a family history of blood clotting conditions).

Other warnings you should know about:

Taking CYKLOKAPRON can cause the following:

- **Allergic reaction:** This can occur when CYKLOKAPRON solution for injection is given intravenously (directly into your bloodstream). Your healthcare professional will closely monitor you after CYKLOKAPRON administration.
- **Seizures (fits)**
- **Thromboembolism** (blood clot in a vein or artery)
- **Vision problems:** This can include blurred vision, loss of vision, and impaired colour vision. If you are prescribed to take CYKLOKAPRON for several weeks, you should get an eye check-up before you start taking CYKLOKAPRON and at regular intervals. These check-ups will assess the sharpness of your vision, colour vision, and field of vision. If you notice any change in your vision, especially in your colour vision, tell your healthcare professional right away.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Pregnancy:

- CYKLOKAPRON can pass through the placenta and harm your unborn baby. If you are able to get pregnant, plan to become pregnant, are pregnant, or are taking hormonal birth control methods, there are specific risks that you must first discuss with your healthcare professional.
- CYKLOKAPRON can affect hormonal birth control methods such as “the pill” and can cause unwanted serious effects. Therefore, you should use a non-hormonal birth control method while you are taking CYKLOKAPRON. If you have any questions about this, talk to your healthcare professional.
- If you become pregnant or think you are pregnant while taking CYKLOKAPRON, tell your healthcare professional right away.

Driving and using machines:

CYKLOKAPRON can cause dizziness. Before you drive or do tasks that require special attention, wait until you know how you respond to CYKLOKAPRON.

Menstrual Periods:

- If you are taking CYKLOKAPRON for heavy periods, you should monitor your menstrual flow. If menstrual bleeding is not reduced after three menstrual cycles, consult with your healthcare professional. They may recommend an alternative treatment.
- CYKLOKAPRON should not be used in children (under 18 years of age) to prevent or reduce bleeding during heavy menstrual periods.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CYKLOKAPRON:

- medicines used to help your blood clot;
- hormonal birth control (e.g., “the pill”);
- anticoagulants used to prevent blood clots and thin the blood;
- hydrochlorothiazide, a diuretic that is typically used to treat high blood pressure;
- desmopressin, a medicine used to treat diabetes;
- sulbactam-ampicillin, an antibiotic used to treat bacterial infections;
- carbazochrome, a medicine used to help your blood clot;
- ranitidine, a medicine used to lower the amount of stomach acid;
- nitroglycerin, a medicine used to treat or prevent chest pain.

How to take CYKLOKAPRON:

- **Tablets:** Take CYKLOKAPRON tablets by mouth exactly as directed by your healthcare professional. Always take the number of tablets your healthcare professional tells you.
- **Solution for Injection:** Your healthcare professional will prepare and give you CYKLOKAPRON solution for injection. You will receive CYKLOKAPRON through your veins (i.e., “intravenously” or “IV”) by slow injection as a bolus IV dose over 5 minutes or as an IV drip. They will ensure that the correct route of administration (IV) is used to give your dose. Other routes of administration are **NOT** to be used as this can cause serious adverse events including death.

Usual dose:

- **Tablets:** The usual adult dose is 2 to 3 tablets (1000 mg to 1500 mg) two to three times a day. The dose for children will be calculated by the healthcare professional based on their body weight.
- **Solution for Injection:** Your healthcare professional will decide the best dose based on weight.

Overdose:

Symptoms of an overdose with CYKLOKAPRON include:

- diarrhea;
- dizziness;
- headache;
- nausea;
- seizures;
- symptoms of low blood pressure (e.g., blurry vision, confusion, fainting, light-headedness, weakness); and
- vomiting.

If you think you, or a person you are caring for, have taken too much CYKLOKAPRON, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose of CYKLOKAPRON tablets, do not take the missed dose. Instead, take the next scheduled dose at the usual time. Do not try to make up for the missed dose by taking extra tablets.

What are possible side effects from using CYKLOKAPRON?

These are not all the possible side effects you may have when taking CYKLOKAPRON. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of CYKLOKAPRON may include:

- diarrhea;
- dizziness, especially if the injection is given too quickly;
- nausea (feeling sick);
- vomiting.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach, vomiting, hives, rash, or swelling of the face, lips, tongue or throat.			√
Eye problems: blurred vision, changes to the sharpness of vision, loss of vision, or colour vision change, changes to the field of vision, or sudden loss of eyesight in one eye.			√
Seizures (fit): loss of consciousness with uncontrollable shaking.			√
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint, or possible irregular heartbeat.			√
Thromboembolism (blood clot in a vein or artery, including in the brain, limbs, and heart): arm or leg pain, tenderness or swelling, skin that is red or warm, coldness, tingling, numbness, pale skin, muscle pain, muscle spasms, weakness, dizziness, numbness, weakness on one side of the body, and problems with talking, writing, or understanding language.			√
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing, difficulty speaking,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking, or loss of balance.			
Acute renal cortical necrosis (death of the tissue in the outer part of the kidney): red or dark brown urine, blood in urine, lower back pain, fever, changes in blood pressure, or urine flow is reduced or stopped.			√
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up and after fast injection).		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Tablets:** Store at room temperature (15°C to 30°C).
- **Solution for Injection:** Store the unopened vials at room temperature (15°C to 30°C). After dilution, the mixture should be immediately used. However, if needed, the mixture can be stored at 2°C to 8°C for up to 24 hours. If the mixture is not used within 24 hours of preparation, it should be discarded.
- Keep out of reach and sight of children.

If you want more information about CYKLOKAPRON:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.pfizer.ca), or by calling 1-800-463-6001.

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