

PART III: CONSUMER INFORMATION

Pr **CYKLOKAPRON®** (Tranexamic acid)

This leaflet is part III of a three-part "Product Monograph" published when CYKLOKAPRON was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CYKLOKAPRON. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

CYKLOKAPRON is a prescription medicine which is used to prevent or reduce bleeding in different conditions. You may have been prescribed it for one of the following:

- After minor surgery such as tooth removal in people with a hereditary blood clotting disorder (haemophilia)
- Cervical surgery (Conization of the cervix)
- Nose bleeds (Epistaxis)
- Heavy periods (menorrhagia)
- Bleeding inside the eye (hyphaema)
- A hereditary disease called angioneurotic oedema - a doctor will have told you if you have this.

What it does:

CYKLOKAPRON belongs to one of a group of medicines called antifibrinolytic agents, which are used to stop excessive bleeding after an operation or to assist with blood clotting. When you bleed your body forms clots as part of healing. In some people these clots do not stay in place long enough. This can cause too much bleeding.

When it should not be used:

Do not take CYKLOKAPRON:

- If you have a history or risk of blood clots (thromboembolism), especially in the leg, lung, brain, or tissues surrounding the brain.
- If you are allergic to tranexamic acid or any of its ingredients or similar medicines
- If you have acquired disturbances of colour vision
- If you have blood in the urine or any bleeding related to the kidney.

What the medicinal ingredient is:

Tranexamic acid

What the non-medicinal ingredients are:

Tablets: cellulose microcrystalline, colloidal silica anhydrous, eudragit E, hydroxypropylcell, magnesium stearate, PEG 8000, Povidone, talcum, titanium dioxide, vanillin.

Solution for injection: water for injection

What dosage forms it comes in:

Tablets: 500 mg

Injection: 100 mg/ ml.

WARNINGS AND PRECAUTIONS

BEFORE you use CYKLOKAPRON talk to your doctor or pharmacist if:

- you have kidney disease. The medicine can accumulate in your body. Therefore a lower dose might be given to you
- you have bleeding from the upper urinary tract. This shows as blood in your urine.
- you have ever had any uncontrollable bleeding (including irregular menstrual bleeding).
- you are pregnant or breastfeeding.
- you are taking "the pill" (hormonal contraceptives) or anticoagulants (drugs to inhibit blood from clotting as much).
- you are being treated for disseminated intravascular coagulation CYKLOKAPRON will only be given if your doctor has done blood tests to check you are suitable, otherwise other anti-clotting medicines may be a better option for you.
- you are obese, diabetic, have been told you have polycystic ovary syndrome a history of cancer of the endometrium in a close relative, are on estrogen therapy or are taking tamoxifen.

Tell your doctor or pharmacists about any prescription and non-prescription medicines you are taking, including natural or herbal remedies.

CYKLOKAPRON is not recommended for children under 18 years of age with abnormally heavy menstrual flow (hypermenorrhea).

CYKLOKAPRON may cause disturbance to your colour vision. If you are to be treated for several weeks with CYKLOKAPRON, it is advisable to have an eye check up (for sharpness of vision, colour vision, field of vision etc.) before you start on CYKLOKAPRON and at regular intervals. If you notice any change in your vision, especially in your colour vision, tell your doctor or pharmacist right away so that they can arrange for you to safely stop taking CYKLOKAPRON.

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 doctor, an alternative treatment may be necessary.

If you experience (feel) dizziness, do not drive or use machinery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any medicines you use including any prescription, over the counter or natural health products.

Drugs that may interact with CYKLOKAPRON include:

- any medicines used to help your blood clot.
- medicines that decrease blood clots (anticoagulants) . Treatment with anticoagulants must take place under the strict supervision of a physician experienced in this field.
- birth control that contains hormones such as “The Pill”. The Pill along with CYKLOKAPRON may increase your chance of having a blood clot, stroke, or heart attack.
- hydrochlorothiazide, desmopressin, sulbactam-ampicillin, carbazochrome, ranitidine, or nitroglycerin. These medicines along with CYKLOKAPRON may lead to heart attacks.

PROPER USE OF THIS MEDICATION

Usual dose:

Take CYKLOKAPRON exactly as directed by your health care professional. Always take the number of tablets your doctor tells you.

The usual adult dose is 2-3 tablets two-three times daily.

Depending on why you have been given these tablets, your dose may be different.

The dose for children is calculated according to body weight (25 mg/kg).

Patients with kidney disease should receive lower doses.

CYKLOKAPRON solution for injection will usually be given to you by slow injection into a vein as a bolus intravenous (IV) dose over 5 minutes or as an IV drip. Your doctor will decide the best dose for you, based on your weight.

It should be inspected visually for clarity, particulate matter, precipitation, discolouration, and leakage prior to administration

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your tablets you should take your next dose as usual. Do not take extra tablets to make up for the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication may cause unwanted effects. However, check with your doctor or pharmacist promptly if any of the following persist or become troublesome:

- Nausea (feeling sick),

- vomiting (being sick) and
- diarrhoea

If the injection is given too quickly, you can feel dizzy due to reduced blood pressure.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency treatment
		Only if severe	In all cases	
Uncommon	Allergic reactions (skin rash, hives, swelling of the face, lips, tongue or throat, and difficulty swallowing or breathing)			✓
	Central retinal artery and vein obstruction. Changes in your eyesight (such as changes to the sharpness of vision or field of vision and especially impaired color vision)		✓	✓
	Dizziness		✓	✓
	Seizures or fits		✓	✓
	Pain in your chest or legs		✓	
	Heart attack (chest pain)		✓	✓
	Blood clots/deep vein thrombosis/arterial thrombosis limb (redness, warmth, swelling in your hands, legs, ankles or feet)		✓	✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency treatment
	Only if severe	In all cases	
Cerebral infarction/cerebrovascular accident/cerebral thrombosis (problems with speech, walking, sudden confusion, numbness or weakness)		✓	✓
Acute renal cortical necrosis (trouble urinating)		✓	✓
Low blood pressure (may occur after fast injection. Symptoms include dizziness, headache, and light headedness especially if you change positions quickly)		✓	

This is not a complete list of side effects. For any unexpected effects while taking CYKLOKAPRON, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15 - 30°C).
Keep your medicine out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 Fax toll-free to 1-866-678-6789, or
 Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 1908C
 Ottawa, Ontario
 K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001

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