Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Cyklokapron?

Cyklokapron contains the active ingredient tranexamic acid. Cyklokapron is used to prevent or reduce excessive bleeding in patients: who experience bleeding inside the eye; that have heavy periods; that experience periodic severe swelling of the throat; after prostate surgery; are undergoing minor surgery and have a blood clotting disorder. For more information, see Section <u>1. Why</u> <u>am I using Cyklokapron?</u> in the full CMI.

2. What should I know before I take Cyklokapron?

Do not use if you have ever had an allergic reaction to tranexamic acid or any of the ingredients listed at the end of the CMI, are being treated for stroke or blood clots or have a problem with colour vision that developed after you were born.

Tell your doctor if you, or someone in your family has ever suffered from blood clots, severe bruising, convulsion, fits or seizures; kidney disease with or without blood in the urine, unexplained irregular periods. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take Cyklokapron? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cyklokapron and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Cyklokapron?

Your doctor will decide how many tablets you need. It will depend on why you are taking this medicine and if you have kidney disease.

More instructions can be found in Section 4. How do I use Cyklokapron? in the full CMI.

5. What should I know while taking Cyklokapron?

Things you	Tell your doctor or dentist that you are taking Cyklokapron.	
should do	Seek medical attention immediately if you develop a sudden severe headache as this may require urgent medical attention and your doctor may stop Cyklokapron.	
Driving or using machines	Cyklokapron may cause dizziness or seizures in some people and may influence the ability to drive or use machines.	
Drinking alcohol	No information available.	
Looking after your medicine	Store below 30°C	

For more information, see Section 5. What should I know while using Cyklokapron? in the full CMI.

6. Are there any side effects?

The side effects include allergic reactions such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing; unexpected pain, swelling, warmth or redness in your legs or arms; convulsions, fits or seizures; giddiness or dizziness; changes in your eyesight including colour vision; blood clot or bleeding in the eye or loss of vision; itchy, red or swollen skin; nausea; vomiting; diarrhoea.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Cyklokapron® Tablets

Active ingredient(s): tranexamic acid

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cyklokapron. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Cyklokapron.

Where to find information in this leaflet:

- 1. Why am I taking Cyklokapron?
- 2. What should I know before I take Cyklokapron?
- 3. What if I am taking other medicines?
- 4. How do I take Cyklokapron?
- 5. What should I know while taking Cyklokapron?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Cyklokapron?

Cyklokapron contains the active ingredient tranexamic acid. Cyklokapron is used to prevent or reduce excessive bleeding in patients: who experience bleeding inside the eye; who have heavy periods; who experience periodic severe swelling of the throat; after prostate surgery; who are undergoing minor surgery and have a blood clotting disorder.

2. What should I know before I take Cyklokapron?

Warnings

Do not use Cyklokapron if you:

- are allergic to tranexamic acid, or any of the ingredients listed at the end of this leaflet.
- are being treated for stroke
- are being treated for blood clots in your legs, lungs or anywhere else in your body.
- have a problem with colour vision that developed after you were born.

Check with your doctor if you:

- or someone in your family has ever suffered from blood clots
- severe bruising
- have or have ever suffered from convulsion, fits or seizures
- kidney disease with or without blood in the urine
- unexplained irregular periods.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Cyklokapron and affect how it works.

- other medicines used to prevent bleeding
- medicines used to thin the blood.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cyklokapron.

4. How do I take Cyklokapron?

How much to take

Follow the instructions provided to you by your doctor or pharmacist and use Cyklokapron until your doctor tells you to stop. Swallow the tablets with water.

Traumatic hyphaema (bleeding inside the eye)

Take 2 or 3 tablets every 8 hours, for 6 to 7 days.

Heavy periods

Take 2 or 3 tablets 4 times a day for four days. Start taking the tablets when you first notice the bleeding. Take CYKLOKAPRON tablets for the first four days of your period. See your doctor for a check up after three months of treatment. If the bleeding is not reduced, talk to your doctor.

Hereditary Angioneurotic Oedema (periodic severe swelling of the throat)

The usual dose is 2 or 3 tablets, 2 to 3 times a day. Your doctor will tell you how long to take the tablets.

For those undergoing prostate surgery

The usual dose is 2 tablets 6 hours before surgery, and then 2 tablets 3 to 4 times a day. Your doctor will tell you how long to take the tablets.

For those with a clotting disorder, having minor surgery

The usual dose is 2 or 3 tablets, 2 to 3 times a day. Your doctor will tell you how long to take the tablets.

The directions your doctor gives you should be strictly followed.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

When to take Cyklokapron

Cyklokapron should be taken regularly at the same time each day.

If you forget to take Cyklokapron

If you miss your dose at the usual time, take your tablet(s) as soon as you remember and then go back to taking it as you normally would. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have taken too much Cyklokapron

If you think that you have used too much Cyklokapron, you may need urgent medical attention.

Symptoms from taking too much or being given too much Cyklokapron include:

- dizziness
- headache
- nausea
- diarrhoea
- low blood pressure
- convulsions, fits or seizures.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or pharmacist
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Cyklokapron?

Things you should do

Remind any doctor or dentist you visit that you are using Cyklokapron.

Seek medical attention immediately if you develop a sudden severe headache as this may require urgent medical attention and your doctor may stop Cyklokapron.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cyklokapron affects you.

Cyklokapron may cause dizziness or seizures in some people

Drinking alcohol

No data available.

Looking after your medicine

Store below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
 Nausea or vomiting diarrhoea 	Speak to your doctor if you have any of these common side effects and they worry you.

Side effects

Side effects	What to do
 sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing, unexpected pain convulsions, fits or seizures swelling, warmth or redness in your legs or arms giddiness or dizziness changes with eyesight including colour vision blood clot or bleeding in the eye or loss of vision itchy, red or swollen skin 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/</u> <u>reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Cyklokapron contains

Active ingredient	tranexamic acid
(main ingredient)	
Other ingredients	Tablet core
	microcrystalline cellulose

(inactive ingredients)	 hyprolose purified talc magnesium stearate colloidal anhydrous silica povidone water. Tablet coating Eudragit E100 titanium dioxide macrogol 8000
	• vanillin

Do not take this medicine if you are allergic to any of these ingredients.

What Cyklokapron looks like

Cyklokapron are white, capsule shaped film-coated tablets that are marked with a line on one side and 'CY' on the other.

Cyklokapron Tablets: AUST R 14463.

Who distributes Cyklokapron

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

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