

CYKLOKAPRON

Tranexamic acid Tablets and Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CYKLOKAPRON. It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with CYKLOKAPRON against the benefits it is expected to have for you.

Please read this leaflet carefully and follow the instructions given to you by your doctor and the advice contained in this leaflet.

If you have any concerns about being treated with this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What CYKLOKAPRON is used for

CYKLOKAPRON Tablets are used to prevent excessive bleeding in patients with:

- traumatic hyphaema (bleeding into the front part of the eye)
- blood clotting disorders, who are having minor surgery
- heavy periods
- hereditary angioneurotic oedema (periodic swelling of the throat)

CYKLOKAPRON Solution for Injection is used to reduce bleeding and the need for transfusion of blood

in patients undergoing heart surgery, total knee replacement and total hip replacement surgery.

How CYKLOKAPRON works

CYKLOKAPRON contains tranexamic acid. Tranexamic acid is an antifibrinolytic that works by slowing the processes that cause bleeding.

Before treatment with CYKLOKAPRON

When CYKLOKAPRON must not be used

CYKLOKAPRON must not be used if you:

- have an allergy 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.

Do not use CYKLOKAPRON after the expiry date (EXP) printed on the pack.

Medicine taken after the expiry date has passed may not work as well.

Do not use CYKLOKAPRON if the packaging is torn or shows signs of tampering.

Do not use CYKLOKAPRON to treat any other complaint unless your doctor tells you to.

Before treatment with CYKLOKAPRON

Tell your doctor if you have any of the following:

- you, or someone in your family, has ever suffered from blood clots
- severe bruising
- kidney disease with or without blood in the urine
- are pregnant or think you may be pregnant
- are breastfeeding or plan to breastfeed
- irregular periods and the reason is not known.

Tell your doctor if you have or have ever suffered from convulsion, fits or seizures before you start taking CYKLOKAPRON.

Convulsions, fits or seizures have been reported with CYKLOKAPRON treatment.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of these things, tell him/her before you start treatment with CYKLOKAPRON.

Do not give this medicine to anyone else even if they have the same condition as you.

Taking other medicines

Tell your doctor about any other medicines you are taking including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop.

Some medicines may interfere with CYKLOKAPRON. These include:

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

These medicines may affect the way CYKLOKAPRON works.

Treatment with CYKLOKAPRON

How to take CYKLOKAPRON Tablets

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Traumatic hyphaema (bleeding to the front part of the eye)

Take two or three tablets every 8 hours, for six to seven days. Swallow the tablets with water.

Heavy periods

Take two or three tablets four 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. Swallow the tablets with water.

Hereditary Angioneurotic Oedema (periodic swelling of the throat)

The usual dose is two or three tablets, 2 to 3 times a day. Your doctor will

tell you how long to take the tablets. Swallow the tablets with water.

For those with a clotting disorder, having minor surgery

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

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.

If you forget to take it

Take your CYKLOKAPRON 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 have missed and take your next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time because this may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Cyklokapron Solution for Injection

Cardiac Surgery and Total Knee or Total Hip Replacement Surgery

CYKLOKAPRON Solution for Injection will be administered under medical supervision to reduce blood loss during cardiac surgery or during your knee or hip replacement surgery.

Your doctor will determine the dose that you will be given, based on your weight. The dose used in children undergoing heart surgery may be different to the dose used in adult heart surgery.

The dose may vary depending on whether you suffer from diseases relating to the kidneys.

If you take or are given too much CYKLOKAPRON (overdose)

CYKLOKAPRON Solution for Injection will be administered under medical supervision so an overdose is unlikely.

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

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

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 13 11 26, in New Zealand telephone 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital if you think you or anyone else has taken too much CYKLOKAPRON, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Have CYKLOKAPRON or this leaflet available to give details if needed.

Keep telephone numbers for these places handy.

While you being treated with CYKLOKAPRON

Things you must do

Tell any other doctors, dentists and pharmacists that you are being treated with CYKLOKAPRON.

If you start on any new medicine, tell your doctor, dentist or

pharmacist that you being treated with CYKLOKAPRON.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you being treated with CYKLOKAPRON.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea.

These are the more common side effects of CYKLOKAPRON.

Mostly these are mild and short-lived.

Following cardiac surgery, total knee replacement or total hip replacement surgery, tell your doctor or nurse immediately if you experience any of the following:

- irregular and often rapid heart beat
- heart attack
- slow or irregular heart beat
- cardiogenic shock caused by very low blood pressure. The symptoms are dizziness and light headedness, rapid, weak pulse, white skin, sweating, restlessness, loss of consciousness, fainting, rapid, shallow breathing, cold clammy skin and weakness
- stroke. The symptoms of stroke are numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech
- kidney problems where you pass little or no urine, drowsiness,

nausea, vomiting and breathlessness

- difficulty breathing
- a condition called deep vein thrombosis (DVT). The symptoms of DVT are pain and swelling in the large veins, usually in your legs. DVT may lead to complications such as blood clots in your lungs
- bowel infarction caused by a restriction of blood supply to the bowels. You may experience severe abdominal pains and may pass bloody stools.

These are serious side effects. You may need urgent medical attention.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- unexpected pain
- unexpected swelling in your legs or arms
- giddiness or dizziness
- allergic skin reactions
- changes in your eyesight
- convulsions, fits or seizures
- low blood pressure from rapid administration of CYKLOKAPRON Solution for Injection.

These may be serious side effects. You may need urgent medical attention.

These side effects are rare.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice any other side effects while being treated with CYKLOKAPRON.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After treatment with CYKLOKAPRON

Storage

Keep your CYKLOKAPRON tablets in a cool, dry place where the temperature stays below 30°C.

Do not store CYKLOKAPRON Tablets or any other medicine in the bathroom or near a sink.

Do not leave your tablets in the car on hot days or on a window sill.

Heat and dampness can destroy some medicines.

Keep your CYKLOKAPRON Tablets out of reach of children.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

CYKLOKAPRON Solution for Injection will normally be stored in a hospital. The undiluted product should be stored in a cool, dry place where the temperature stays below 25°C. Do not freeze. Protect from light.

This product does not contain antimicrobial agents. It is for single use in one patient only.

If storage of the diluted solution is necessary, it should be stored at 2°C-8°C for a maximum of 24 hours. Any unused solution should be discarded.

Disposal

If your doctor or pharmacist tells you to stop taking CYKLOKAPRON Tablets or the medicine has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Remember: this medicine is for you. Never give it to someone else even if they have the same condition as you.

Product Description

What it looks like

CYKLOKAPRON Tablets are white, capsule shaped tablets. The tablets are scored on one side and marked with 'CY' on the other.

CYKLOKAPRON Solution for Injection is a clear and colourless solution.

Ingredients

The active ingredient in CYKLOKAPRON is tranexamic acid.

Each CYKLOKAPRON tablet contains 500 mg of tranexamic acid.

The inactive ingredients are:

- microcrystalline cellulose
- hydroxypropylcellulose
- talc
- magnesium stearate
- colloidal anhydrous silica
- povidone
- water.

Other ingredients that are in the tablet coating are:

- Eudragit E100
- titanium dioxide
- macrogol 8000
- vanillin.

CYKLOKAPRON Tablets do not contain gluten, sucrose, tartrazine or other azo dyes.

CYKLOKAPRON Solution for Injection each contains 100 mg/mL tranexamic acid.

The inactive ingredient is

- Sterile Water for Injections.

Pack sizes

CYKLOKAPRON Tablets are available in bottles of 100 tablets.

CYKLOKAPRON Solution for Injection is available in packs of

- 5 x 5 mL and 10 x 5 mL ampoules each containing 500 mg tranexamic acid and 5 mL Water

for Injections (not available in Australia).

- 1 x 10 mL and 10 x 10 mL ampoules each containing 1000 mg tranexamic acid and 10 mL Water for Injections.

If you want to know more

If you have any questions about your treatment with CYKLOKAPRON, ask your doctor or pharmacist.

Supplier

In Australia by

Pfizer Australia Pty Ltd
38-42 Wharf Road
WEST RYDE NSW 2114
Australia
Toll free number: 1800 675 229.

In New Zealand by

Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand
Toll Free Number: 0800 736 363.

Australian Registration Number

Tablets

- 500 mg tablet - AUST R 14463.

Solution for Injection

- 500 mg/5 mL ampoule - AUST R 160658 (not available in Australia).
- 1000 mg/10 mL ampoule - AUST R 166415.

This leaflet was prepared in December 2013.

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