

## PATIENT INFORMATION LEAFLET

CYKLOKAPRON IV 500 should only be administered intravenously and should not be administered intrathecally or epidurally.

In order to reduce the risk of fatal medication errors due to incorrect route of administration of CYKLOKAPRON IV 500, it is strongly recommended to label the syringes containing CYKLOKAPRON.

**SCHEDULING STATUS:** **S4**

**CYKLOKAPRON® IV 500, 500 mg/ 5 mL injection**

**Tranexamic acid**

**Sugar free**

**Read all of this leaflet carefully before you receive CYKLOKAPRON IV 500**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CYKLOKAPRON IV 500 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What CYKLOKAPRON IV 500 is and what it is used for
2. What you need to know before you receive CYKLOKAPRON IV 500
3. How to receive CYKLOKAPRON IV 500
4. Possible side effects
5. How to store CYKLOKAPRON IV 500

## 6. Contents of the pack and other information

### 1. What CYKLOKAPRON IV 500 is and what it is used for

CYKLOKAPRON IV 500 injection contains tranexamic acid which forms part of a group of medicines called antifibrinolytics which reduce the dissolution of clotted blood.

CYKLOKAPRON IV 500 is used to reduce bleeding for a short period of time. You may have been prescribed it for one of the following:

- Prostate or bladder surgery
- Nose bleeds (epistaxis)
- Abnormalities of the cervix
- Bleeding inside the eye (hyphaema)
- Tooth removal (dental extraction) in haemophiliacs
- A hereditary disease called angioedema
- Heavy periods / severe menstrual bleeding (menorrhagia)

### 2. What you need to know before you receive CYKLOKAPRON IV 500

#### Do not receive CYKLOKAPRON IV 500:

- if you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of CYKLOKAPRON IV 500 (listed in section 6)
- if you have (or have had in the past) medical problems due to abnormal blood clots (hypercoagulopathies) or active clotting
- if you have a history of blood clots in your arteries or veins
- if you have a colour vision disorder or pronounced clotting tendency
- if your liver is not functioning properly
- if you have bleeding inside your skull
- if you have a massive upper urinary tract bleeding
- if you have inflammation of the wall of a vein

Due to the risk of seizures and brain swelling, CYKLOKAPRON IV 500 must not be given into the spine, epidurally (around the spinal cord) or into the brain.

### **Warnings and precautions**

CYKLOKAPRON IV 500 is ONLY to be given to you through a vein either by intravenous infusion (IV) or intravenous injection (IV push). Serious harms have been reported when CYKLOKAPRON IV 500 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 health care provider immediately.

### **Tell your doctor or health care provider before receiving the injection:**

- if you have had convulsions (fits). Your doctor must use the minimal dose possible to avoid convulsions following treatment with CYKLOKAPRON
- if you have blood in your urine
- if you have ever had any uncontrollable bleeding
- if you have been receiving CYKLOKAPRON every day for a long time. If so, you may need to have regular eye tests and blood tests to check your vision
- if you have kidney failure, kidney disease or a kidney disorder due to the risk of accumulation
- if you are pregnant, likely to be pregnant or breastfeeding
- if you are taking any other medicines

Please consult your doctor if any of the above apply to you or have applied to you at any time in the past.

### **Other medicines and CYKLOKAPRON IV 500**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving CYKLOKAPRON IV 500.

CYKLOKAPRON IV 500 may pass into your baby through your breast milk. You should not breastfeed your infant when you are using CYKLOKAPRON IV 500.

### **Driving and using machines**

CYKLOKAPRON IV 500 may cause dizziness and may influence the ability to drive or use machines.

It is not always possible to predict to what extent CYKLOKAPRON IV 500 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYKLOKAPRON IV 500 affects them.

### **3. How to receive CYKLOKAPRON IV 500**

You will not be expected to give yourself CYKLOKAPRON IV 500. It will be given to you by a person who is qualified to do so.

CYKLOKAPRON IV 500 injection will be given to you by slow injection or infusion, only into a vein (blood vessel) and should not be given by any other routes. The amount of CYKLOKAPRON IV 500 you receive and for how long will depend on your particular condition.

CYKLOKAPRON IV 500 must not be injected into a muscle or into the spine.

The doctor may also decide to mix this medicine with other solutions which will then be given to you as a drip.

If you need to be treated for more than a few days, your doctor may decide to give you CYKLOKAPRON tablets.

If you have the impression that the effect of CYKLOKAPRON IV 500 is too strong or too weak, tell your doctor or pharmacist.

**If you receive more CYKLOKAPRON IV 500 than you should**

Since a health care provider will administer CYKLOKAPRON IV 500, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you forget to receive CYKLOKAPRON IV 500**

Since a health care provider will administer CYKLOKAPRON IV 500, it is unlikely that the dose will be missed.

**4. Possible side effects**

CYKLOKAPRON IV 500 can have side effects.

Not all side effects reported for CYKLOKAPRON IV 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CYKLOKAPRON IV 500, please consult your doctor, pharmacist or other health care provider for advice.

Tell your doctor if you notice any of the following:

*Frequent side effects*

- nausea, vomiting, diarrhoea

*Less frequent side effects*

- allergic skin reactions
- thromboembolic events (e.g. formation of a blood clot)
- transient disturbance or impairment of colour vision

- giddiness or feeling dizzy

*Other side effects:*

- sudden, severe allergic reactions
- convulsions (fits)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CYKLOKAPRON IV 500.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via [ZAF.AEReporting@pfizer.com](mailto:ZAF.AEReporting@pfizer.com).

### **5. How to store CYKLOKAPRON IV 500**

- Store all medicines out of reach of children.
- Store at room temperature at or below 25 °C and protect from light.
- Do not use CYKLOKAPRON IV 500 after the expiry date which is printed on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What CYKLOKAPRON IV 500 contains**

- The active ingredient is tranexamic acid. Each CYKLOKAPRON IV 500 ampoule contains 500 mg tranexamic acid.

- The other ingredient is water for injections.

### **What CYKLOKAPRON IV 500 looks like and contents of the pack**

CYKLOKAPRON IV 500 injection is a clear, colourless solution.

CYKLOKAPRON IV 500 injection is packaged in small glass containers called ampoules. Each ampoule contains 5 ml solution and each box contains 5 ampoules.

### **Holder of Certificate of Registration**

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

### **This leaflet was last revised in**

10 September 2025

### **Registration number**

H/8.1/806