PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CYKLOKAPRON® T 500, 500 mg/ film-coated tablet

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you start taking CYKLOKAPRON T 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 T 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 T 500 is and what it is used for

CYKLOKAPRON T 500 tablets contain tranexamic acid which forms part of a group of medicines called antifibrinolytics which reduce the dissolution of clotted blood.

CYKLOKAPRON T 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 take CYKLOKAPRON T 500

Do not take CYKLOKAPRON T 500:

- if you are hypersensitive (allergic) to tranexamic acid or to any of the other ingredients of CYKLOKAPRON T 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

Warnings and precautions

Take special care with CYKLOKAPRON T 500:

- 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 taking this medicine 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 T 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 taking CYKLOKAPRON T 500.

CYKLOKAPRON T 500 may pass into your baby through your breastmilk. You should not breastfeed your infant when you are taking CYKLOKAPRON T 500.

Driving and using machines

CYKLOKAPRON T 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 T 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 T 500 affects them.

3. How to take CYKLOKAPRON T 500

Do not share medicines prescribed for you with any other person.

Always take CYKLOKAPRON T 500 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Follow your doctor's instructions on how many CYKLOKAPRON T 500 tablets to take, when to take them and for how long.

The usual adult dosage is 2 – 3 tablets two to three times daily. Depending on why you have been given these tablets, your dose may be different. The tablets should be taken with a glass of water. The tablets should be swallowed whole. Do not crush or chew them.

The dose will be reduced if you have kidney disease.

Your doctor will tell you how long your treatment with CYKLOKAPRON T 500 will last. Do not stop treatment early.

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

If you take more CYKLOKAPRON T 500 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CYKLOKAPRON T 500

If you forget to take your CYKLOKAPRON T 500 tablets you should take your next dose as usual. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CYKLOKAPRON T 500 can have side effects.

Not all side effects reported for CYKLOKAPRON T 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CYKLOKAPRON T 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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CYKLOKAPRON T 500.

5. How to store CYKLOKAPRON T 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 T 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 T 500 contains

- The active substance is tranexamic acid. Each CYKLOKAPRON T 500 tablet contains 500 mg tranexamic acid.
- The other ingredients in CYKLOKAPRON T 500 tablets are microcrystalline cellulose, hydroxypropylcellulose, talc, magnesium stearate, colloidal anhydrous silica and povidone. The tablets are coated with methacrylate polymers, titanium dioxide, talc, magnesium stearate, polyethylene glycol and vanillin.

What CYKLOKAPRON T 500 looks like and contents of the pack

CYKLOKAPRON T 500 tablets are white capsular, film coated tablets, with arcs above and below the letters “CY” engraved on one side and scored on the other side.

CYKLOKAPRON T 500 tablets are packaged in plastic containers of 24 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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