Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cyklokapron 500 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg Tranexamic Acid.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet
White, capsule-shaped, film coated tablet with the letters CY with arcs above and below on one side and scored on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Short-term use for haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in the following conditions:

  Prostatectomy and bladder surgery
  Menorrhagia
  Epistaxis
  Conisation of the cervix
  Traumatic hyphaema

- Hereditary angioneurotic oedema

- Management of dental extraction in haemophiliacs

- Management of upper gastrointestinal haemorrhage

4.2 Posology and method of administration

Route of Administration: Oral

Local fibrinolysis: The recommended standard dosage is 15-25mg/kg body weight (2-3tablets) 2-3 times daily. For the indications listed below the following doses may be used:

Prostatectomy: Prophylaxis and treatment of haemorrhage in high risk patients should commence per-or-post operatively with Cyklokapron Injection; thereafter 2 tablets (l.0g) 3-4 times daily until macroscopichaematuria is no longer present.

- **Menorrhagia:** 2-3 tablets (l.0-1.5g) 3-4 times daily for 3-4 days. Cyklokapron therapy should be initiated only after heavy bleeding has started.

- **Epistaxis:** Where recurrent bleeding is anticipated oral therapy (2 (l.0g) tablets 3 times daily) should be administered for 7 days.

- **Conisation of the cervix:** 3 (1.5g) tablets 3 times daily.

- **Traumatic hyphaema:** 2-3 (l.0-1.5g) tablets 3 times a day. The dose is based on 25mg/kg 3 times a day.

Hereditary angioneurotic oedema: 2-3 tablets 2-3 times daily intermittently for some days, or continuously, depending on whether or not the patient has prodromal symptoms.

Haemophilia: In the management of dental extractions 2-3 (l.0-1.5g) tablets every eight hours. The dose is based on 25 mg/kg.

Upper gastrointestinal haemorrhage: 10ml Cyklokapron Injection by slow intravenous injection every 6 hours for the first 3 days, then 2-3 (l.0-1.5g) tablets orally every 6 hours for a further 3-4 days.

Children: In children, for current approved indications as described in section 4.1, the dosage is in the region of 20 mg/kg/day. However, data on efficacy, posology and safety for these indications are limited.

Elderly patients: No reduction in dosage is necessary unless there is evidence of renal failure.

Renal impairment
For patients with renal impairment, the dosage of tranexamic acid should be reduced according to the blood creatinine level.

Serum creatinine µmol/L	Oral dose	Administration
120-249	15 mg/kg body weight	Every 12 hours

4.3 Contraindications

Cyklokapron Tablets are contraindicated in patients with:
- Severe renal impairment (the risk of accumulation)
- Subarachnoid haemorrhage. The limited clinical experience shows that a reduced risk for re-bleeding is off set by an increase in the rate of cerebral ischemia.
- History of venous or arterial thrombosis
- Fibrinolytic conditions following consumption coagulopathy
- History of convulsions
- Hypersensitivity to tranexamic acid or any of the other ingredients.

4.4 Special warnings and precautions for use

In patients with renal insufficiency a reduction in dosage is recommended (see Section 4.2 Posology and Administration) because of the risk of accumulation.

Tranexamic acid should be used with caution in massive haematuria from the upper urinary tract (especially in haemophilia) since in a few cases ureteric obstruction has been reported (i.e. formation of a ureteral clot).

Tranexamic acid should be used with caution when intravascular coagulation is in progress.

Patients witha high risk of thrombosis (a previous thromboembolic event and a family history of thromboembolic disease) should use Cyklokapron Tablets only if there is a strong medical indication and under strict medical supervision.

Patients with irregular menstrual bleeding should not use Cyklokapron Tablets until the cause of the irregularity has been established. Clinical experience with Cyklokapron in menorrhagic children under 15 years is not available.

Before use of Cyklokapron, risk factors of thromboembolic disease should be investigated.

Tranexamic acid should be administered with care in patients receiving oral contraceptives because of the increased risk of thrombosis.

Convulsions
In patients with a history of convulsion, tranexamic acid should not be administered.

Cases of convulsions have been reported in association with tranexamic acid treatment. In cardiac surgery, most of these cases were reported following intravenous (i.v) injection of tranexamic acid in high doses.

4.5 Interaction with other medicinal products and other forms of interaction

Cyklokapron will counteract the thrombolytic effect of fibrinolytic preparations.

4.6 Fertility, pregnancy and lactation

There is no evidence from animal studies of a teratogenic effect. Clinical use in pregnant women is limited and as tranexamic acid passes the placenta it should not be used during pregnancy unless considered essential by the physician.

Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/l0), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports, not known (cannot be estimated from the available data).

Immune system disorders
Very rare: Hypersensitivity reactions including anaphylaxis

Eye disorders
Rare: Colour vision disturbances, retinal/artery occlusion

Cardio-vascular disorders
Very Rare: malaise with hypotension, with or without loss of consciousness (generally following too fast intravenous injection, exceptionally after oral administration)

Vascular disorders
Rare: Thromboembolic events
Very rare: Arterial or venous thrombosis at any sites

Gastro-intestinal disorders
Very rare: Digestive effects such as nausea, vomiting and diarrhoea, may occur but disappear when the dosage is reduced

Nervous system disorders
Very Rare: Convulsions, particularly in case of misuse (see section 4.3 Contraindications and 4.4 Precautions and warnings)
Not known: Convulsions particularly in case of misuse (refer to sections 4.3 and 4.4)

Skin and subcutaneous tissue disorders
Rare: Allergic skin reactions

Postmarketing Surveillance:
Rare cases of adverse events have been reported with use of tranexamic acid; thromboembolic events, impaired colour vision and other visual disturbances and dizziness.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No cases of overdosage have been reported. Signs and symptoms may include dizziness, headache, hypotension and convuslsions. It has been shown that convulsions tend to occur at higher frequency with increasing dose of tranexamic acid. Initiate vomiting, then stomach lavage, and charcoal therapy.Maintain a high fluid intake to promote renal excretion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The inhibitory effect of tranexamic acid in plasminogen activation by urokinase has been reported to be 6-100 times and by streptokinase 6-40 times greater than that of aminocaproic acid.The antifibrinolytic activity of tranexamic acid is approximately ten times greater than that of aminocaproic acid.

5.2 Pharmacokinetic properties

Absorption
Peak plasma Tranexamic acid concentration is obtained immediately after intravenoius administration (500mg). Then concentration decreases until the 6th hour. Elimination half-life is about 3 hours.

Distribution
Tranexamic acid administered parenterally is distributed in a two compartment model. Tranexamic acid is delivered in the cell compartment and the cerebrospinal fluid with delay. The distribution volume is about 33% of the body mass. Tranexamic acid crosses the placenta, and may reach one hundredth of the serum peak concentration in the milk of lactating women.

Elimination
Tranexamic acid is excreted in urine as unchanged compound. 90% of the administered dose is excreted by the kidney in the first twelve hours after administration (glomerular excretion without tubularre absorption).
Following oral administration, 1.13% and 39% of the administered dose were recovered after 3 and 24 hours respectively.
Plasma concentrations are increased in patients with renal insufficiency.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Microcrystalline cellulose (E460)
Hyprolose (E463)
Talc (E553b)
Magnesium stearate (E572)
Silica anhydrous, colloidal
Povidone (E1201)

Film-coating
Methacrylate copolymers (Eudragit E100)
Titanium dioxide (E171)
Macrogol 8000
Vanillin
Talc (E553b)
Magnesium stearate (E3572)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years in blisters.
5 years in polyethylene container.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White, high density polyethylene containers with white, medium density polyethylene screw caps and polyethylene tamper-proof membranes, containing 50 tablets.
Or
PVC/PVDC blister strips with aluminium foil backing (60 tablets).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste should be disposed of in accordance with local requirements.

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Viatris Healthcare Limited
Damastown Industrial Park
Mulhuddart
Dublin 15
Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23355/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

February 2025