SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cyklo-f 500 mg film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains tranexamic acid 500 mg
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film coated tablet
White, capsular, engraved with a score and with arcs above and below the letters CY.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Menorrhagia

4.2. Posology and method of administration

Posology

Recommended dosage is 2 tablets 3 times daily as long as needed for up to 4 days. If very heavy menstrual bleeding, dosage may be increased. A total dose of 4 g daily (8 tablets) should not be exceeded. Treatment with Cyklo-f should not be initiated until menstrual bleeding has started.

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

Serum creatinine μmol/L	**Oral dose**	**Administration**
120–249	15 mg/kg body weight	Every 12 hours
250–500	15 mg/kg body weight	Every 24 hours

Method of administration
Oral use.

4.3. Contraindications

Cyklo-f for menorrhagia is contraindicated in women with:

- Active thromboembolic disease.
- History of convulsions.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Patients with irregular menstrual bleeding should not use Cyklo-f until the cause of irregular bleeding has been established.
If menstrual bleeding is not adequately reduced by Cyklo-f, an alternative treatment should be considered.

Patients with a previous thromboembolic event and a family history of thromboembolic disease (patients with thrombophilia) should use Cyklo-f only if there is a strong medical indication and under strict medical supervision.

Renal impairment
In patients with renal insufficiency/impairment because of the risk of accumulation of tranexamic acid, serum creatinine levels should be monitored. (For dosage administration see section 4.2).

The use of tranexamic acid in cases of increased fibrinolysis due to disseminated intravascular coagulation is not recommended.

In haematuria from the upper urinary tract clot formation can, in a few cases, lead to ureteric obstruction.

Convulsions
Cases of convulsions have been reported in association with tranexamic acid treatment, most of these cases were reported following intravenous injection in high doses.

Paediatric population
Clinical experience with Cyklo-f in menorrhagic children under 15 years of age is not available.

4.5. Interaction with other medicinal products and other forms of interaction

Clinically important interactions have not been observed with tranexamic acid tablets. Due to the absence of interaction studies, simultaneous treatment with anticoagulants must be under the strict supervision of a physician experienced in coagulation.

4.6. Fertility, pregnancy and lactation

Cyklo-f is intended for treatment of menorrhagia only; it should not be used during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

Adverse reactions like, for example, dizziness that can affect the ability to drive and use machines have been reported.

4.8. Undesirable effects

Dose-dependent gastrointestinal discomfort is the most commonly reported undesirable effect, but it is usually of mild and temporary nature.

Tabulated list of adverse reactions
Adverse reactions frequency is defined using the following convention:
Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Frequency of undesirable effects at a dose of 4 g/day (MedDRA LLT):

Organ Class	**Frequency**		
	Common	*Uncommon*	*Not known*
Nervous system disorders	Dizziness, Headache		Convulsions (refer to sections 4.3 and 4.4)
Gastrointestinal disorders	Vomiting, Diarrhoea, Nausea, Abdominal pain		
Renal and urinary disorders			Acute renal cortical necrosis
Skin and subcutaneous tissue disorders		Allergic skin reaction	Fixed drug eruption
Eye disorders			Impaired colour vision and other visual disturbances
Vascular disorders			Thromboembolic events

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 the national reporting system listed in Appendix V.*

4.9. Overdose

Symptoms: Dizziness, headache, nausea, diarrhoea, hypotension. Orthostatic symptoms, myopathy and convulsions may occur. Increased risk of thrombosis in predisposed individuals.

Treatment of overdose: Initiate vomiting, then gastric lavage, charcoal therapy and symptomatic treatment. Maintain adequate diuresis. Anticoagulant treatment should be considered.

Toxicity: 37 g of tranexamic acid caused mild intoxication in a seventeen-year-old after gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antifibrinolytics, ATC code: B02A A02

Cyklo-f contains tranexamic acid, an antifibrinolytic which is an inhibitor of the activation of plasminogen to plasmin in the fibrinolytic system. The treatment of menorrhagia is symptomatic since it does not affect the underlying pathogenesis of the increased menstrual flow.

5.2. Pharmacokinetic properties

The bioavailability is approximately 35 % in the dose range of 0.5 – 2 g and it not affected by simultaneous food intake. Following a single oral dose, C_{max} and urinary excretion increased linearly with doses between 0.5 g and 2 g. Following a single oral dose of 0.5 g, C_{max} is approx. 5 microg/ml and after a dose of 2 g C_{max} is 15 microg/ml.
Therapeutic concentration is maintained in plasma up to 6 hours after an oral single dose of 2 g. Binding to plasma proteins (plasminogen) is approximately 3% at therapeutic plasma levels. Plasma clearance is approximately 7 l/hour. Prevailing plasma half-life is approximately 2 hours following a single intravenous dose. After repeated oral administration the half-life is longer. The terminal half-life is about 3 hours. Approximately 95% of the absorbed dose is excreted unchanged in the urine. Two metabolites have been identified: an N-acetylated and a deaminated derivative. Impaired kidney function constitutes a risk for accumulation of tranexamic acid.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans in addition to those included in other sections of studies of safety pharmacology, repeated dose toxicity, toxicity to reproduction, genotoxicity and carcinogenicity.
Retinal abnomalities were found in long term toxicity studies in dog and cat: increased reflectivity, photoreceptor segment atrophy, peripheral retinal atrophy, atrophy of rods and cones. These ocular changes were dose related and occurred in high doses.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Tablet core:
Cellulose, microcrystalline
Hyprolose
Talc
Magnesium stearate
Silica, colloidal anhydrous
Povidone

Tablet coating:
Methacrylate copolymer
Titanium dioxide (E171)
Talc
Magnesium stearate
Macrogol 8000

Vanillin

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

No special precautions for storage.

6.5. Nature and contents of container

Carton containing 18 tablets or 20 tablets in a blister (PVC/PVDC/Aluminium)

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Viatris AB
Box 23033
104 35 Stockholm

8. MARKETING AUTHORISATION NUMBER

12624

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1997-01-31
Date of latest renewal: 2007-01-31

10. DATE OF REVISION OF THE TEXT

2026-05-27