SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tranexamic acid 1000 mg coated granules in sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of coated granules contains tranexamic acid 1000 mg as the active ingredient.
Excipient with known effect: sucrose (450 mg per sachet).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated granules in sachet.

White to off-white coated granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicine is indicated in the reduction of heavy menstrual bleeding (menorrhagia) over several cycles in women with regular, 21-35 day cycles with no more than 3 days individual variability in cycle duration.

4.2 Posology and method of administration

Posology

Recommended dosage is 1 sachet 3 times daily as long as needed for up to 4 days (1 sachet every 6 to 8 hours). If very heavy menstrual bleeding, dosage may be increased. A total dose of 4 g daily (4 sachets) should not be exceeded. Treatment with this medicine should not be initiated until menstrual bleeding has started.

Renal impairment
By extrapolation from clearance data relating to the intravenous dosage form, the following reduction in the oral dosage is recommended for patients with mild to moderate renal insufficiency.

Serum creatinine	*Dose tranexamic acid*

(micromole/l)

120-249	Body weight 60kg and above: 15 mg/kg body weight twice daily Body weight below 60kg: 15 mg/kg body weight once daily
250-500	Body weight 60kg and above: 15 mg/kg body weight once daily Body weight below 60kg: 15 mg/kg body weight once every other day

The maximum dose at each administration in subjects with renal impairment is 1000 mg. Therefore, do not use more than 1 sachet per dose.

Paediatric population
Clinical experience with this medicine in menorrhagic children under 15 years of age is not available.

Method of administration
Oral use.
Coated granules may be taken with a glass of water.
Mixing with semi-solid food has not been studied.

4.3 Contraindications

This medicine for menorrhagia is contraindicated in women with:
- Active thromboembolic disease,
- Severe renal impairment (risk of accumulation),
- History of convulsions,
- Patients taking combined hormonal contraceptives,
- 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 this medicine until the cause of irregular bleeding has been established.
If menstrual bleeding is not adequately reduced by this medicine, an alternative treatment should be considered.

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

Patients experiencing heavy bleeding during hormonal contraceptive use should not start treatment with tranexamic acid, but are advised to contact their Healthcare Professional.

The blood levels are increased in patients with renal insufficiency. Therefore a dose reduction is recommended (see 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.

Excipients:
This medicinal product contains sucrose.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

This medicine is intended for treatment of menorrhagia only; it should not be used during pregnancy.

Pregnancy
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of tranexamic acid in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). However, this medicine is intended for treatment of menorrhagia only; it is not intended to be used during pregnancy.

Lactation
Tranexamic acid has been detected in breast milk of women at concentrations one hundredth of the serum peak concentration. Tranexamic acid is excreted in

breast milk, but a risk for an impact on the child seems unlikely at therapeutic doses. Breastfeeding can therefore be continued during this medicine therapy.

Fertility
There are no clinical or pre-clinical data on the effect of tranexamic acid on fertility.

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		
Skin and subcutaneous tissue disorders		Allergic skin reaction	Fixed drug eruption
Eye disorders			Impaired colour vision and other visual disturbances

Vascular disorders			Thromboembolic events
Renal and urinary disorders			Acute renal cortical necrosis

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 Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

This medicine 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

Absorption
The bioavailability is approximately 35 % in the dose range of 0.5 – 2 g and is not affected by simultaneous food intake.

Distribution

Binding to plasma proteins (plasminogen) is approximately 3% at therapeutic plasma levels.

Tranexamic acid crosses the placenta, and may reach one hundredth of the serum peak concentration in the milk of lactating women

Biotransformation
Two metabolites have been identified: an N-acetylated and a deaminated derivative.

Elimination
Therapeutic concentration is maintained in plasma up to 6 hours after an oral single dose of 2 g.
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.
Plasma clearance is approximately 7 l/hour.
Approximately 95% of the absorbed dose is excreted unchanged in the urine.

Linearity/non-linearity
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 Cmax is 15 microg/ml.

Renal impairment
Impaired kidney function constitutes a risk for accumulation of tranexamic acid.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Retinal abnormalities 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

Sugar spheres (sucrose, maize starch)

Povidone K30 (E1201)
Sucralose (E955)
Silica colloidal anhydrous (E551)
Polyacrylate dispersion 30 per cent
Talc (E553B)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Coated granules in sachet (LDPE / Aluminium / LDPE / Paper).
Box of 12 sachets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

CEMAG CARE
55 rue de Turbigo,
75003 Paris,
France.

8 MARKETING AUTHORISATION NUMBER(S)

PL 46938/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/04/2025

10 DATE OF REVISION OF THE TEXT

28/04/2026