SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tranexamic Acid 500mg Tablets

Evana Heavy Period Relief 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of tranexamic acid.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Description: White to off-white caplet shaped tablets marked TXA 26 on one face and blank on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reduction of heavy menstrual bleeding 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
Treatment with tranexamic acid is initiated only once heavy bleeding has started. The recommended dosage is 2 tablets 3 times daily as long as needed but for a maximum of 4 days. If there is very heavy menstrual bleeding, the dosage may be increased. A total dose of 4g daily (8 tablets) should not be exceeded.

Tranexamic acid can be used as long as periods remain regular and heavy.

Elderly:
Not recommended for use in the elderly.

Children:
Not for use in children and adolescents under 18 years of age.

Method of Administration
Route of administration: Oral

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients listed in section 6.1
- Mild to moderate renal insufficiency
- Severe renal impairment (risk of accumulation)
- Active thromboembolic disease
- A previous thromboembolic event and a family history of thrombophilia
- Haematuria
- Irregular menstrual bleeding
- Patients taking warfarin or other anticoagulants
- Patients taking oral contraceptives because of the increased risk of thrombosis
- Fibrinolytic conditions following disseminated intravascular coagulation
- History of convulsions.

4.4 Special warnings and precautions for use

Patients should consult their doctor if menstrual bleeding is not reduced after three menstrual cycles.

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

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

The following patients should consult their doctor prior to taking the product:

- Women over the age of 45 years
- Patients who are obese or diabetic
- Those with polycystic ovary syndrome or a history of endometrial cancer in a first-degree relative
- Women receiving unopposed oestrogen or tamoxifen.

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

The blood levels are increased in patients with renal insufficiency. Therefore, a dose reduction is recommended (see section 4.2).

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

Patients who experience visual disturbance should stop taking the product.

Clinical experience with tranexamic acid in menorrhagic children under 15 years of age is not available.

In case of haematuria of renal origin (especially in haemophilia), there is a risk for urinary obstruction at the lower levels of the tract. If left untreated, urinary obstruction may lead to serious consequences such as renal insufficiency, urinary tract infection, hydronephrosis, and anuria. Therefore, close monitoring is recommended for those patients with haematuria or risk of haematuria from the upper urinary tract.

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.

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Tranexamic acid will counteract the thrombolytic effect of fibrinolytic preparations.

4.6 Fertility, pregnancy and lactation

Pregnancy

Tranexamic acid is contraindicated in pregnancy. Although there is no evidence from animal studies of a teratogenic effect, the usual caution with use of drugs in pregnancy should be observed. Tranexamic acid crosses the placenta.

Breastfeeding
Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. An antifibrinolytic effect in the infant is unlikely.

Breastfeeding women should consult their doctor prior to taking tranexamic acid.

4.7 Effects on ability to drive and use machines

Tranexamic acid has no or negligible influence on the ability to drive and use machines. Visual disturbances may occur following administration of tranexamic acid.

4.8 Undesirable effects

Gastrointestinal discomfort is the most common undesirable effect that may occur but disappears when the dosage is reduced.

Immune system disorders
Very rare (<1/10,000): Hypersensitivity reactions including anaphylaxis.

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

Gastrointestinal disorders
Common (≥1/100 to <1/10): Nausea, vomiting, diarrhoea.

Skin and subcutaneous tissue disorders
Uncommon (≥1/1,000 to <1/100): Allergic skin reactions.

Adverse Events:
Other adverse events have been reported with the use of tranexamic acid, but the frequency of the reports cannot be estimated from the available data: thromboembolic events, retinal/artery occlusion and impaired colour vision or other visual disturbances, seizures particularly in cases of misuse (refer to sections 4.3 and 4.4).

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

Signs

Signs and symptoms may include nausea, vomiting, orthostatic symptoms and / or hypotension, dizziness, headache and convulsions.

Management

Initiate vomiting, then stomach lavage and charcoal therapy. Maintain a high fluid intake to promote renal excretion. There is a risk of thrombosis in predisposed individuals. Anticoagulant treatment should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihemorrhagics, Antifibrinolytics. ATC code: B02AA02

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.

A 2001 study involving more than 800 women demonstrated a significant improvement in their quality of life when taking tranexamic acid.

5.2 Pharmacokinetic properties

Absorption
Peak plasma Tranexamic acid concentration is obtained immediately after intravenous 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 tubular reabsorption).

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 pre-clinical 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

Calcium hydrogen phosphate (anhydrous), croscarmellose sodium, povidone, talc and magnesium stearate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original pack.

6.5 Nature and contents of container

Blister packs of white PVC coated with PVdC and hard-tempered aluminium foil on the reverse, in cardboard boxes of 18 tablets.

6.6 Special precautions for disposal

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Manx Healthcare Ltd,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 14251/0300

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/05/2023

10 DATE OF REVISION OF THE TEXT

17/01/2025