SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tranexamic Acid 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg tranexamic acid

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Short-term use for haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis.

- Local fibrinolysis occurs in the following conditions:

Prostatectomy
Menorrhagia
Epistaxis
Conisation of the cervix

Traumatic hyphaema

Management of dental extraction in haemophiliacs

- Hereditary angioneurotic oedema

4.2 Posology and method of administration

Posology

Adults:

The recommended standard dose is 15-25 mg / kg body weight (which generally equates to 2 to 3 tablets), two to three times a day.

The following doses are also suggested for the listed indications:

Prostatectomy:

Prophylaxis and treatment of haemorrhage in high-risk patients should commence pre or post operatively with tranexamic acid injection. Thereafter 2 tablets should be dosed three to four times a day until macroscopic haematuria is no longer present.

Menorrhagia:

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 4g daily (8 tablets) should not be exceeded. Treatment with tranexamic acid should not be initiated until menstrual bleeding has started.

Epistaxis:

2 tablets should be dosed three times a day for seven days where recurrent bleeding is anticipated.

Conisation of the cervix:

3 tablets should be dosed three times a day.

Traumatic hyphaema:

2 to 3 tablets should be dosed three times a day. This dose should be based on a dose of 25 mg / kg body weight three times a day.

Hereditary angioneurotic oedema:

2 to 3 tablets should generally be dosed two to three times a day. In some patients this dosing should be continuous, but intermittent treatment can be used where patients are aware of the onset of the illness.

Haemophilia:

2 to 3 tablets should be dosed three times a day in the management of dental extractions. Again, this dose should be based on a dose of 25 mg / kg body

weight.

Renal insufficiency:
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 (µmol/1)	Dose tranexamic acid
120-249	15 mg/kg body weight/twice daily
250-500	15 mg/kg body weight/day.

Elderly:

No reduction in dosage is necessary unless there is any evidence of renal failure.

Children:

This should be calculated according to body weight at 25 mg/kg per dose. However, data on efficacy, posology and safety for these indications are limited.

Method of Administration
Route of administration: Oral

4.3 Contraindications

Tranexamic acid is contraindicated in patients with:

- Hypersensitivity to tranexamic acid or any of the excipients listed in section 6.1
- Severe renal impairment because of the risk of accumulation
- Active thromboembolic disease
- History of venous or arterial thrombosis
- Fibrinolytic conditions following disseminated intravascular coagulation
- History of convulsions

4.4 Special warnings and precautions for use

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.

In the long-term treatment of patients with hereditary angioneurotic oedema, regular eye examinations (e.g. visual acuity, slit lamp, intraocular pressure, visual fields) and liver function tests should be performed.

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.

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 be withdrawn from treatment.

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

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

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.

Breast feeding

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.

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 my occur following administration of tranexamic acid.

4.8 Undesirable effects

Adverse events reported 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 vein/artery occlusion

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

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

Skin and subcutaneous tissue disorders
Rare: Allergic skin reactions

Nervous system disorders

Frequency not known: Convulsions 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 and symptoms may include nausea, vomiting, orthostatic symptoms and/or hypotension, dizziness, headache and convulsions. 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: B02A A02.

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 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 60 tablets

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Manx Healthcare Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 14251/0026

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 June 2008/7 April 2009

10 DATE OF REVISION OF THE TEXT

14/08/2024