

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Tranexamic Acid Rivopharm 500 mg film coated tablets.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film coated tablet contains:

Tranexamic acid 500 mg.

For a full list of excipients, see 6.1.

### **3 PHARMACEUTICAL FORM**

Tablets.

Tranexamic Acid Rivopharm 500 mg film coated tablets are white to off white, capsule shaped, biconvex film-coated tablets. They are marked with TXA 500 with a break line.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Tranexamic Acid Rivopharm 500 mg film coated tablets are indicated for short term use for haemorrhage or risk of haemorrhage in those with increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in the following conditions:

1.
  - a) Prostatectomy and bladder surgery
  - b) Menorrhagia
  - c) Epistaxis
  - d) Conisation of the cervix
  - e) Traumatic hyphaema
2. Management of dental extraction in haemophiliacs.
3. Hereditary angioneurotic oedema.

#### **4.2 Posology and method of administration**

Route of administration: Oral.

Adults:

Local Fibrinolysis: The recommended standard dose is 15-25mg/kg bodyweight (i.e. 2-3 tablets) two to three times daily. For the indications listed below the following doses may be used:

- 1a. Prostatectomy: Prophylaxis and treatment of haemorrhage in high risk patients should commence per- or post-operatively with an injectable form; thereafter 2 tablets three to four times daily until macroscopic haematuria is no longer present.
- 1b. 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.
- 1c. Epistaxis: When repeated bleeding is anticipated oral therapy (2 tablets three times daily) should be administered for 7 days.
- 1d. Cervix Conisation: 3 tablets three times daily
- 1e. Traumatic Hyphaema: 2-3 tablets 3 times daily. The dose is based on 25mg/kg three times a day.
2. Haemophilia: In the management of dental extractions 2-3 tablets every eight hours. The dose is based on 25mg/kg.
3. Hereditary angioneurotic oedema: Some patients are aware of the onset of illness; suitable treatment for these patients is intermittently 2-3 tablets two to three times daily for some days. Other patients are treated continuously at this dosage.

Children:

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

Elderly:

No reduction in dosage is necessary unless there is evidence of renal failure (see guidelines below).

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( $\mu\text{mol/l}$ )	Oral Dose	Dose Frequency
120-249	15 mg/kg body weight	twice daily
250-500	15 mg/kg body weight	daily

### 4.3 Contraindications

Severe renal failure impairment because of risk of accumulation.

Hypersensitivity to tranexamic acid or any of the other ingredients

Active thromboembolic disease.  
History of venous or arterial thrombosis  
Fibrinolytic conditions following consumption coagulopathy  
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 coagulation 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 the 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**

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 may occur following administration of tranexamic acid.

## 4.8 Undesirable effects

Adverse effects have been ranked under headings of frequency using the following convention:

Very common ( $\geq 1/10$ )
Common ( $\geq 1/100, < 1/10$ )
Uncommon ( $\geq 1/1000, < 1/100$ )
Rare ( $\geq 1/10,000, < 1/1,000$ )
Very rare ( $< 1/10,000$ ) including isolated reports
Not known (cannot be estimated from the available data).

The following undesirable effects have been reported

### **Immune system disorders**

*Very rare:* Hypersensitivity reactions including anaphylaxis

### **Gastrointestinal disorders**

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

### **Nervous system disorders**

*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.

*Not known:* Fixed drug eruption

**Vascular disorders**

*Rare:* thromboembolic events.

*Very rare:* Arterial or venous thrombosis at any sites

**Eye disorders**

*Rare:* colour vision disturbances, retinal/artery occlusion

**Renal and urinary disorders**

*Not known:* 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 ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)).

**4.9 Overdose**

Signs and symptoms may include nausea, diarrhoea, 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: 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.

**5.2 Pharmacokinetic properties**

Tranexamic acid crosses the blood barrier.

**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 twelve first 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 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: Cellulose microcrystalline, povidone (K 90), croscarmellose sodium, silica colloidal anhydrous, talc, magnesium stearate;

Film coating: methacrylate polymers, titanium dioxide (E171), talc, magnesium stearate, macrogol (8000).

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Do not store above 30°C. Store in the original package.

**6.5 Nature and contents of container**

The blister pack (PVC/aluminium) contains 60 tablets.

**6.6 Special precautions for disposal**

There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Rivopharm UK Ltd  
100 Bishopsgate  
London  
EC2N 4AG  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 33155/0010

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

24/10/2024

**10 DATE OF REVISION OF THE TEXT**

08/03/2026