

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Tranexaminezuur Midas 1000 mg, omhuld granulaat 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

Tranexaminezuur Midas 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 Tranexaminezuur Midas 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 (micromole/l)    Dose tranexamic acid*

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 per dosing moment in patients with renal impairment is 1000 mg. Therefore, do not use more than 1 sachet at every dosing moment.

##### Paediatric population

Clinical experience with Tranexaminezuur Midas 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. Any mixing outside the recommendations is the responsibility of the healthcare professional or the user.

### **4.3 Contraindications**

Tranexaminezuur Midas 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 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.

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.

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.

#### Visual disturbances

Attention should be paid to possible visual disturbances including visual impairment, vision blurred, impaired colour vision and if necessary, the treatment should be discontinued.

#### Excipients:

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

Tranexaminezuur Midas 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, Tranexaminezuur Midas 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 Tranexaminezuur Midas 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 ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  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		
	<i>Common</i>	<i>Uncommon</i>	<i>Not known</i>
<b><i>Nervous system disorders</i></b>	Dizziness, Headache		Convulsions (refer to sections 4.3 and 4.4)
<b><i>Gastrointestinal disorders</i></b>	Vomiting, Diarrhoea, Nausea, Abdominal pain		
<b><i>Skin and subcutaneous tissue disorders</i></b>		Allergic skin reaction	Fixed drug eruption
<b><i>Eye disorders</i></b>			Impaired colour vision and other visual disturbances
<b><i>Vascular disorders</i></b>			Thromboembolic events
<b><i>Renal and urinary disorders</i></b>			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 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

Tranexaminezuur Midas 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  $C_{max}$  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, 24, 36, 48 or 72 sachets. Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7. MARKETING AUTHORISATION HOLDER**

MIDAS Pharma GmbH  
Rheinstraße 49  
West  
55218 Ingelheim am Rhein  
Duitsland

## **8. MARKETING AUTHORISATION NUMBER(S)**

RVG 134772

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

Datum van eerste verlening van de vergunning: 23 maart 2026

**10. DATE OF REVISION OF THE TEXT**