SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tafixyl 500 mg Film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500 mg tranexamic acid.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

Capsule shape and biconvex film-coated tablets with a break mark on one side and embossed "500" on the other side.

The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Primary hyperfibrinolysis or fibrinogenolysis with bleeding or risk of bleeding.

2. Secondary fibrinolysis. This can occur, for example in:

Local fibrinolysis:

a. menorrhagia
b. prostatectomy and bladder surgery
c. conisation of the cervix for suspected carcinoma *in situ*
d. tooth extraction in patients with haemophilia A and haemophilia B.

3. Hereditary angioedema.

Tafixyl is indicated for use in adults. There is no clinical experience available regarding the use of Tafixyl in children or adolescents below 15 years of age.

4.2 Posology and method of administration

Posology

Local fibrinolysis: the recommended dosage is 1-1.5 g, 2-3 times daily.

For the indications below, the following standard dosages can be used:

1a. Menorrhagia (essential or after IUD insertion):
1-1.5 g orally 3-4 times daily for three to four days. Treatment with Tafixyl is initiated when bleeding becomes profuse.

1b. Prostatectomy and bladder surgery:
Dosing is usually preceded by single intravenous administration with tranexamic acid. Subsequently, it is recommended 1 g orally 3-4 times daily until macroscopic haematuria no longer occurs.

1c. Conisation:
1.5 g orally 3 times daily for 12-14 days postoperatively.

1d. Tooth extraction:
In patients with coagulation disorders. Dosing is usually preceded by single intravenous administration with tranexamic acid.
After the procedure, 25 mg/kg is given orally 3-4 times daily for 6-8 days.

2. Hereditary angioedema:
1-1.5 g orally 2-3 times daily. Tafixyl is given intermittently or continuously, depending on the fact whether or not the patient has prodromal symptoms.

Renal insufficiency
In cases of renal insufficiency, the dosage should be adjusted according to serum creatinine levels, in accordance with the table below:

Serum creatinine	oral dose
120-249 µmol/L	15 mg/kg, twice daily
250-500 µmol/L	15 mg/kg, every 24 hours
> 500 µmol/L	7.5 mg/kg, every 24 hours

Paediatric population
The dose for this age group 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.

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

Method of administration

Film-coated tablets should be taken whole with sufficient quantity of liquid (e.g. one glass of water).

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
Active thromboembolic diseases, such as deep vein thrombosis, pulmonary embolism and cerebral thrombosis.
Subarachnoid bleeding. Limited clinical experience indicates that a reduced risk of recurrent bleeding is offset by an increase in the rate of cerebral ischaemia.

4.4 Special warnings and precautions for use

Blood levels are elevated in patients with renal insufficiency. A dose reduction is therefore recommended (see section 4.2 Posology and method of administration).

Patients at high risk of thrombosis (a history of thromboembolic disease and a family history of thromboembolic disease) should take Tafixyl only if there is a strong medical indication and under close medical supervision.

Use in cases of disseminated intravascular coagulation is potentially dangerous and can cause severe thrombosis. If Tafixyl must be given, this should be undertaken in conjunction with heparin.

In the event of haematuria from the upper urinary tract, thrombus formation can in some cases lead to ureteral obstruction.

In rare cases, blindness and changes in colour perception have occurred. This usually improves upon discontinuation of the medication.

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

There is no clinical experience with Tafixyl in adolescents with menorrhagia below 15 years.

4.5 Interaction with other medicinal products and other forms of interaction

To date, no interactions with Tafixyl have been observed which are of any clinical relevance.
Due to the lack of research into these interactions, concomitant treatment with anticoagulants should proceed only under the strict monitoring of a physician experienced in this field.
Tafixyl must not be given concomitantly with chlorpromazine in subarachnoid bleeding.
Tafixyl may reduce the efficacy of thrombolytic treatment (streptokinase, alteplase, anistreplase).

4.6 Fertility, pregnancy and lactation

Pregnancy
The amount of data on the use of tranexamic acid in pregnant women is limited or non-existent.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
As a precautionary measure, it is preferable to avoid the use of Tafixyl during pregnancy, unless absolutely necessary.
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. No risk to newborns / infants can be excluded.
Tafixyl should not be used during breast-feeding unless absolutely necessary.

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

4.7 Effects on ability to drive and use machines

Tafixyl has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Frequencies are defined as follows:
Very common (≥1/l0),
Common (≥1/100 and <1/10),
Uncommon (≥1/1000 and <1/100),
Rare (≥ 1/10,000 and <1/1000),

Skin and subcutaneous tissue disorders

Uncommon: allergic skin reactions

Gastrointestinal disorders
Common: nausea, vomiting, diarrhoea

Eye disorders
Rare: colour vision disorders and other visual disturbances (see section 4.4, Special warnings and precautions for use)

Ear and labyrinth disorders
Rare: dizziness

Blood and lymphatic system disorders
Rare: thrombotic and embolic events, such as pulmonary embolism and stroke. Thrombocytopenia and development of pathological bleeding time (see section 4.4, Special warnings and precautions for use)

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 requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective national regulatory authorities.

4.9 Overdose

Symptoms of overdose
The Symptoms of overdose include: nausea, diarrhoea, dizziness, headache, orthostatic complaints, hypotension and myopathy. There is a risk of thrombosis in predisposed patients.

In one 17-year old person for instance, mild signs of intoxication occurred after oral ingestion of 37 grams of tranexamic acid following gastric lavage.

Treatment of an overdose
The treatment should be symptomatic in nature. In this context, adequate diuresis must be ensured. Treatment with anticoagulants must be considered. If high doses of Tafixyl have been ingested, the following measures may be useful: stimulation of gag reflex, gastric lavage, treatment with activated charcoal. Such measures must be weighed against the stress that this sort of treatment engenders.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifibrinolytics.
ATC code: B02AA02

Tafixyl contains tranexamic acid (AMCA), which exerts a strong inhibitory effect on plasminogen activation in the fibrinolytic system, i.e. the conversion of plasminogen to plasmin. The antifibrinolytic effect of tranexamic acid on the fibrinolysis caused by urokinase or tissue activators is approximately 10 times more potent per gram than that of epsilon aminocaproic acid. Tranexamic acid is used in fibrinolytic bleeding which may occur in a variety of clinical situations where there is stimulation of the activator mechanism.

5.2 Pharmacokinetic properties

The bioavailability of Tafixyl film-coated tablets is approximately 35% at a dosage of 0.5 - 2.0 grams and is independent of concomitant food intake. Following oral administration, C_{max} and renal excretion increases linearly with doses between 0.5 and 2 grams. C_{max} is approximately 5 µg/mL after single oral administration of 0.5 grams tranexamic acid and 15 µg/mL after the ingestion of 2 grams. After single oral administration of 2 g tranexamic acid, therapeutic concentrations in plasma are maintained for 6 hours. At therapeutic plasma levels, plasma protein binding (plasminogen) is approximately 3%. Plasma clearance is approximately 7 L/h. Following single intravenous administration, the plasma half-life is approximately 2 hours. After repeated oral administration, the half-life is prolonged. The terminal half-life is approximately three hours. Approximately 95% of the absorbed dose is excreted unchanged in the urine.

After repeated administration of 10-20 mg/kg, antifibrinolytic active levels of tranexamic acid are maintained for 7-8 hours in serum, up to 17 hours in tissues and up to 48 hours in the urine.

Two metabolites have been identified: an N-acetyl and a D-amine derivative. If renal function is impaired, there is a risk of tranexamic acid accumulation.

5.3 Preclinical safety data

Other than the data included in other sections of this summary of product characteristics, non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

In long-term toxicological studies in dogs and cats, retinal changes were observed, such as increased reflectivity, photoreceptor segment atrophy, peripheral retinal atrophy and atrophy of rods and cones. The changes were dose-dependent and occurred at high doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Microcrystalline cellulose
Low substituted hydroxypropylcellulose
Talc
Magnesium stearate
Colloidal anhydrous silica
Povidone K30

Coating
Eudragit Epo Ready Mix:
Basic butylated methacrylate copolymer

Sodium laurylsulphate
Stearic acid
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store below 30°C. Store in the original package.

6.5 Nature and contents of container

Tafixyl 500 mg film-coated tablets are packed in PVC-Alu blisters and HDPE containers with LDPE/HDPE cap, without desiccant.

Blisters: 20, 30, 60 and 100 film-coated tablets

HDPE containers: 20, 30, 60 and 100 film-coated tablets

The product is placed in a carton box along with a package leaflet.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

Pharma Bavaria Internacional (PBI) Portugal Unipessoal Lda.
Rua do Monte Leite, 498-1ºDto.
2765-496 Estoril - Portugal
Tel: +351214682905
e-mail: info@pharma-bavaria.com

8. MARKETING AUTHORISATION NUMBER(S)

CTD8699

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

May 2026

10. DATE OF REVISION OF THE TEXT

May 2026