APPROVED
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INSTRUCTION
for medical use

VIDANOL®

***Composition*:**
active substance: tranexamic acid;
1 tablet contains tranexamic acid 500 mg;
excipients: microcrystalline cellulose, low substituted hydroxypropyl cellulose, povidone K30, croscarmellose sodium, anhydrous colloidal silicon dioxide, talc, magnesium stearate, Colorcoat FC4S white: hydroxypropyl methylcellulose, diethylftalat, hydrogenated castor oil powder, stearic acid, talc, titanium dioxide (E 171).

Pharmaceutical form. Coated tablets.
Basic physical and chemical properties: white, circular, biconvex coated tablets, plain on both sides.

Pharmacotherapeutic group.
Antihemorrhagic agents. Fibrinolysis inhibitors. Code ATC B02A A02.

Pharmacological properties.
Pharmacodynamics.
Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At high 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. Tranexamic acid also has anti-allergic and anti-inflammatory effects by inhibiting the formation of kinins and other active peptides involved in allergic and inflammatory reactions.
Pharmacokinetics.
Absorption. Peak plasma tranexamic acid concentration is obtained immediately after intravenous administration (500 mg). Then concentration decreases until the 6th hour. Elimination half-life is about 3 hours.
Distribution. Tranexamic acid administered parenterally is distributed in two directions: absorbed with a delay into the cerebrospinal fluid and into the cells. The distribution volume is about 33% of the body mass.
Tranexamic acid can penetrate the placental barrier, and in breast milk of lactating women, its concentration can reach about 1/100 C_{max}.
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 of tranexamic acid are increased in patients with renal insufficiency.

Clinical particulars.

Indications.

Short term use for haemorrhage or risk of haemorrhage in those with increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in such conditions:

- prostatectomy and bladder surgery;
- menorrhagia;
- epistaxis;
- conisation of the cervix;
- posttraumatic hyphaema.

Hereditary angioneurotic oedema.
Dental extraction in haemophiliacs.

Contraindications.

- Hypersensitivity to tranexamic acid or any of the other ingredients.
- Severe renal impairment (because of risk of accumulation).
- Acute thromboembolic diseases.
- History of venous or arterial thrombosis.
- Fibrinolytic conditions following consumption coagulopathy.
- History of convulsions.

Interaction with other medicinal products and other forms of interaction.

Tranexamic acid counteracts thrombolytic effect of fibrinolytic preparations.

Special warnings and precautions for use.

In case of haematuria of renal origin (especially in haemophilia), there is a risk of lower urinary tract obstruction due to blood clot formation. If left untreated, obstruction can lead to serious consequences such as renal failure, urinary tract infection, hydronephrosis, and anuria. Therefore, close monitoring is recommended for patients with haematuria or at risk of upper urinary tract haematuria.
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 (liver 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.
Since tranexamic acid levels may be increased in patients with renal insufficiency, a dose reduction is recommended (see “Administration details and dosage” section).

The use of tranexamic acid in cases of increased fibrinolysis due to disseminated intravascular coagulation is not recommended.
In case of visual disturbance treatment should be discontinued.
Clinical experience with tranexamic acid in menorrhagia children under 15 years of age is not available.
Cases of seizures 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.
Excipients
This medicinal product contains hydrogenated castor oil, which may cause stomach upset and diarrhoea. This medicinal product contains less than 1 mmol (23 mg)/per sodium dose, i.e. essentially sodium-free.

Pregnancy and lactation.
Pregnancy.
Although preclinical studies in animals have not revealed a teratogenic effect of tranexamic acid on fetal development, it is recommended to follow general recommendations for the use of drugs during pregnancy. 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.

Effects on ability to drive and use machines
Tranexamic acid has no or negligible effect on the ability to drive and use machines. Visual disturbances may occur after the use of tranexamic acid.

Posology and method of administration
The drug is administered orally by adults. The drug is administered without regard to meals.
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:

- *Prostatectomy*: prophylaxis and treatment of haemorrhage in high risk patients should commence per- or postoperatively with an injectable form. Then – in the form of 1 g tablets (2 tablets of 500 mg) 3–4 times a day until the macroscopic hematuria disappears.
- *Menorrhagia*: the recommended dosage is 1 g (2 tablets of 500 mg) 3 times for up to 4 days. If very heavy menstrual bleeding, dosage may be increased, but a total dose of 4 g daily (8 tablets of 500 mg) should not be exceeded. Treatment with the medicinal product should not be initiated until menstrual bleeding has started.
- *Epistaxis:* in case of periodic bleeding – 1 g (2 tablets of 500 mg) 3 times a day for 7 days.
- *Cervix conisation:* 1.5 g (3 tablets of 500 mg) 3 times a day.
- *Posttraumatic hyphaema:* 1–1.5 g (2–3 tablets of 500 mg) 3 times a day. The dose is 25 mg/kg 3 times a day.

Hereditary angioneurotic oedema: some patients are aware of the onset of illness; 1–1.5 g (2–3 tablets of 500 mg) 2–3 times a day for several days is usually sufficient. Other patients should take the drug at the same dose for a long time, depending on the course of the disease.
Tooth extraction in patients with haemophilia: 25 mg/kg (2–3 tablets of 500 mg) every 8 hours.

Patients with renal failure.
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	Oral dose
120–249 μmol/l	15 mg/kg 2 times per day
250–500 μmol/l	15 mg/kg every 24 hours

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

Pediatric population.
The drug is intended for use in adult patients.
There is no clinical experience with the use of tranexamic acid in children and adolescents under 15 years of age.
The dose for this group of patients should be calculated according to body weight of 25 mg/kg per dose. However, data on dosage, efficacy and safety for these indications are limited.

Overdose
Symptoms: nausea, diarrhea, vomiting, abdominal pain, orthostatic symptoms and/or hypotension, dizziness, headache and seizures.
Treatment: initiate vomiting, gastric lavage, use of activated charcoal. It is necessary to use large amounts of fluid to promote renal excretion. There is a risk of thrombosis in susceptible individuals. Symptomatic treatment and, if necessary, anticoagulant therapy are initiated.

Undesirable effects
The adverse reactions listed below are classified according to their frequency and the organ or system organ class affected. The frequency is defined as: very common (≥1/10), 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.
Visual organs disorders:
Rare: colour-vision defect, retinal artery occlusion.
Vascular effects disorders:
Rare: thromboembolic disorders.
Very rare: arterial or venous thrombosis of any location.
Digestive system disorders:
Very rare: nausea, vomiting, diarrhea disappearing after dose reduction.
Skin and subcutaneous tissue:
Rare: allergic skin reactions.
Nervous system disorders:
Frequency unknown: seizures, especially in cases of incorrect use (see sections “Contraindications” and “Special warnings and precautions for use”).
Reporting of suspected adverse reactions.
Reporting of adverse reactions after the registration of a medicinal product is important. This allows monitoring of the benefit/risk ratio when using this medicinal product. Medical and pharmaceutical professionals, as well as patients or their legal representatives, should report

all cases of suspected adverse reactions and lack of efficacy of a medicinal product via the Automated Information System for Pharmacovigilance at the link: https://aisf.dec.gov.ua.

Shelf life. 3 years

Storage conditions.
Store at a temperature not more than 25°C.
Keep out of the reach of children.

Package.
10 tablets are in blister; 3 or 6 blisters are in a carton pack.

Conditions of supply. By prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Address.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

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