VANAXAMIC CAPSULES

Tranexamic Acid 500 mg
Oral capsules | Pack size: 10 x 10

DOSAGE AND ADMINISTRATION

Adults: Dosage varies substantially by indication and regional authorization. For heavy menstrual bleeding, some 500 mg oral product references use 1 g (two 500 mg units) three times daily for up to four days, starting when bleeding begins; other approved regimens differ. Do not extrapolate the US 650 mg tablet regimen to 500 mg capsules. For other indications, the prescriber must determine dose and duration. Use only the dosing schedule approved for Vanaxamic.

PRECAUTIONS

Investigate irregular menstrual bleeding before treatment. Evaluate unexplained haematuria, particularly upper urinary tract bleeding, because clot formation can obstruct urinary flow. Consider risks in disseminated intravascular coagulation, except in specialist-managed cases with predominant fibrinolysis.

OVERDOSAGE

Symptoms may include nausea, vomiting, dizziness, hypotension and potentially seizures or thrombosis. Seek urgent medical attention. Management is supportive, with consideration of renal function.

PRESENTATION

Vanaxamic Capsules 500 mg: 10 x 10 capsules.

COMPOSITION

Each capsule contains Tranexamic Acid 500 mg. Other ingredients: as per the approved Vanaxamic formulation.

RENAL IMPAIRMENT

Tranexamic acid is predominantly eliminated unchanged by the kidneys. Reduce dose and/or extend dosing interval according to renal function and the locally approved product information. Avoid accumulation in significant renal impairment; severe renal impairment may be contraindicated under some product labels.

WARNINGS: THROMBOEMBOLISM

Blood clots, including deep-vein thrombosis, pulmonary embolism and retinal vascular occlusion, have been reported. Seek emergency attention for chest pain, breathlessness, leg swelling, sudden vision loss or neurological deficits. Assess thrombotic risk before prescribing.

DRUG INTERACTIONS

Combined hormonal contraceptives increase thrombotic risk and must not be combined for heavy menstrual bleeding under US product labeling. Caution with prothrombotic agents such as factor IX complex concentrates, anti-inhibitor coagulant concentrates and oral tretinoin. Discuss all current medicines with the prescriber.

STORAGE

Store according to the approved Vanaxamic product label, protected from moisture and excessive heat. Keep out of reach of children. Do not use after the expiry date.

THERAPEUTIC CLASS

Antifibrinolytic agent; haemostatic medicine.

INDICATIONS

Treatment or prevention of bleeding associated with local or generalized fibrinolysis when oral tranexamic acid is appropriate. Depending on local approval, uses may include heavy menstrual bleeding, epistaxis, certain dental procedures in patients with bleeding disorders and other fibrinolytic bleeding conditions. The underlying cause of abnormal bleeding should be evaluated.

CONTRAINDICATIONS

Hypersensitivity to tranexamic acid or any ingredient; active thromboembolic disease; a history of or significant predisposition to thrombosis where contraindicated by local labeling. Combined hormonal contraceptives are contraindicated with oral tranexamic acid for heavy menstrual bleeding under US labeling. Assess severe renal impairment, seizure history and other product-specific contraindications.

ADVERSE REACTIONS

Nausea, vomiting, diarrhea, abdominal discomfort, headache and dizziness may occur. Less common but serious effects include thrombosis, visual disturbances, seizures and hypersensitivity reactions. Stop treatment and seek urgent care for severe allergic symptoms or suspected clot.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.

PHARMACOLOGY

Tranexamic acid is a synthetic lysine analogue that inhibits the activation of plasminogen to plasmin and inhibits plasmin activity at higher concentrations. It reduces breakdown of fibrin clots and thereby helps control bleeding associated with increased fibrinolysis.

METHOD OF ADMINISTRATION

For oral use only. Swallow capsules with water, with or without food unless the approved formulation specifies otherwise. Do not take more than prescribed. If a dose is missed, take it when remembered unless near the next dose; do not double doses.

WARNINGS: VISION AND SEIZURES

Visual disturbances, including changes in colour vision, may occur. Stop treatment and obtain medical evaluation for new visual symptoms. Seizures have been reported, especially with high systemic exposure; use particular caution in renal impairment and in patients with seizure risk.

PREGNANCY AND LACTATION

Use during pregnancy only when a clinician considers it necessary for a specific indication. Tranexamic acid crosses the placenta. Small amounts may be present in breast milk; weigh treatment benefit and potential infant risk. Do not self-medicate during pregnancy.