Tranexamic Acid Tablets BP 500 mg

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

TRANEXAMIC ACID TABLETS BP 500 MG

2. Composition:

Each Film Coated Tablet Contains:
Tranexamic Acid BP..... 500 mg.
Excipients ..... Q.S.
Colour: Titanium Dioxide

3. Pharmaceutical Form:

Solid Oral

4. Clinical Particulars

4.1 Indication

- Short-term use for haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in the following conditions:

  Prostatectomy and bladder surgery

  Menorrhagia

  Epistaxis

  Conisation of the cervix

  Traumatic hyphaema

- Hereditary angioneurotic oedema
- Management of dental extraction in haemophiliacs
- Management of upper gastrointestinal haemorrhage

4.2 Posology and Administration

Take it with food to avoid getting an upset stomach.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients.

Severe renal failure because of risk of accumulation.

Active thromboembolic disease.

History of venous or arterial thrombosis

Fibrinolytic conditions following consumption coagulopathy

History of convulsions

4.4 Special Warning & precautions for use

In case of haematuria of renal origin (especially in haemophilia), there is a risk of mechanical anuria due to formation of a ureteral clot.

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.

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Patients who experience visual disturbance should be withdrawn from treatment.

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

The usual caution with use of drugs in pregnancy should be observed.

Tranexamic acid crosses the placenta.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Most undesirable effects are Hypersensitivity, nausea, vomiting and diarrhoea etc.

4.9 Overdose

Signs and symptoms may include nausea, 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: antifibrinolytic agent, ATC code: B02AA02

Mechanism of action

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

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 crossed 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

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline cellulose

Starch

Sodium starch glycolate

PVPK 30

Purified water

Colloidal silicon dioxide

Purified Talc

Magnesium stearate

Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30 º C. Protect from light. Do not freeze.

6.5 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 Holder

Wings Pharm Africa Ltd

20, Ogunaike Street, Palmgrove, Lagos State, Nigeria

8. Manufacturer

BLUTRIS HEALTHCARE PRIVATE LIMITED

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