**SCHEDULING STATUS:** **S4**

**PROPRIETARY NAME AND DOSAGE FORM:**

CYKLOKAPRON® T 500 Tablets

CYKLOKAPRON® IV 500 Injection

**COMPOSITION**:

Each tablet contains 500 mg tranexamic acid.

Each 5 ml ampoule contains 500 mg tranexamic acid.

**PHARMACOLOGICAL CLASSIFICATION**:

A 8.1 Coagulants, haemostatics

**PHARMACOLOGICAL ACTION**:

CYKLOKAPRON contains tranexamic acid (AMCA), which exerts an inhibitory effect on the activation of plasminogen in the fibrinolytic system, i.e. on the conversion of plasminogen to plasmin.

CYKLOKAPRON is used in fibrinolytic bleeding conditions, which may occur in a number of different clinical conditions in which there is abnormal stimulation of the activation mechanism.

CYKLOKAPRON is absorbed very well by mouth. CYKLOKAPRON is excreted unchanged through the kidneys.

**INDICATIONS**:

1. Short term use in the treatment of hyphaema and in patients with established coagulopathies who are undergoing minor surgery.
2. Management of dental extraction in haemophiliacs.
3. Hereditary angioneurotic oedema.
4. Menorrhagia

**CONTRAINDICATIONS**:

In cases of massive upper urinary tract haemorrhage, antifibrinolytics should be avoided to reduce the risk of ureteric obstruction.

Patients with a pronounced thrombotic tendency or colour vision disorder should not be given CYKLOKAPRON.

Thrombophlebitis, impaired liver function and subarachnoid bleeding.

**WARNINGS AND SPECIAL PRECAUTIONS:**

The safety of CYKLOKAPRON has not been established in pregnancy.

Tranexamic acid passes into breast milk at a concentration of a hundredth of the corresponding serum levels. Caution should be exercised when CYKLOKAPRON is given to nursing women.

For patients in renal failure, CYKLOKAPRON should be given with caution because of the risk of accumulation.

Dosages should be reduced in patients with renal impairment. For patients with moderate to severe impaired renal function, the following dosages are recommended.

| Serum creatinine (μmol/l) | Oral Dose | Intravenous Dose |
|---|---|---|
| 120 - 250 | 15 mg/kg body weight twice daily | 10 mg/kg body weight twice daily |
| 250 - 500 | 15 mg/kg body weight daily | 10 mg/kg body weight daily |
| > 500 | 7,5 mg/kg body weight daily | 5 mg/kg body weight daily |

Patients with a previous history of thromboembolic disease should not be given CYKLOKAPRON unless simultaneous treatment with anticoagulants can be given.

For patients who are to receive continuous treatment with CYKLOKAPRON for longer than several days, an ophthalmological examination is advisable (including visual acuity, colour vision, eye-grounds, field of vision), before commencing treatment, and at regular intervals during treatment.

Medicines with actions on haemostasis should be given with caution to patients on antifibrinolytic therapy. The potential for thrombus formation may be increased by oestrogens, for example, or the action of the antifibrinolytic antagonised by compounds such as the thrombolytics.

**DOSAGE AND DIRECTIONS FOR USE**:

Tranexamic acid is given orally or by slow intravenous infusion/injection. Administration by injection is usually changed to oral administration after a few days.

**Traumatic hyphaema:**

1,0 to 1,5 g every 8 hours for six to seven days.

**Patients with established coagulopathies undergoing minor surgery:**

Conization of the cervix: 1,0 to 1,5 g (2 to 3 tablets) every 8 to 12 hours for 12 days post-operatively.

**Dental operations/extractions:**

25 mg/kg orally two hours before the operation. Factor VIII and Factor IX should be given as well as tranexamic acid. After the operation, 25 mg/kg of tranexamic acid is given 3 to 4 times a day for 6 to 8 days.

**Hereditary angioneurotic oedema:**

Some patients are aware of the onset of illness; a suitable treatment for these patients is 1,0 - 1,5 g two to three times daily for some days. Other patients are treated continually at this dosage.

**Menorrhagia:**

Two to three coated tablets (1 – 1,5 g) three to four times daily, given at the onset of heavy bleeding for the duration of the period.

**For the injection:**

CYKLOKAPRON solution for injection is administered intravenously by slow injection over a period of at least five minutes. For intravenous infusion, CYKLOKAPRON solution for injection may be mixed with electrolyte solutions, carbohydrate solutions, Aminosol and dextran solutions.

Heparin solutions may be added to CYKLOKAPRON solution for injection. CYKLOKAPRON solution for injection should not be mixed with blood and infusion solutions containing penicillin.

**SIDE EFFECTS:**

Gastro-intestinal disorders (nausea, vomiting, diarrhoea) may occur. Cases of giddiness have been reported. Transient disturbance of colour vision may occur. Patients who experience disturbances of colour vision should be withdrawn from treatment.

Rapid intravenous injection may cause dizziness and/or hypotension.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**:

Symptoms of overdosage: Dizziness, headache, nausea and vomiting, diarrhoea.

Faintness and hypotension may occur.

Treatment would consist of procedures to remove unabsorbed drug from the stomach (initiating vomiting, institution of gastric lavage, charcoal therapy) and symptomatic treatment.

Maintain adequate diuresis (with fluids plus diuretics).

The only symptoms of overdosage might be nausea and vomiting and perhaps faintness and hypotension. Treatment would consist of initiating vomiting (to remove unabsorbed drug from the stomach) and enhancing diuresis (with fluids plus diuretics).

**IDENTIFICATION**:

| | |
|---|---|
| CYKLOKAPRON Tablets: | White, capsular, film coated tablets, with arcs above and below the letters 'CY' engraved on one side and scored on the other. |
| CYKLOKAPRON Ampoules: | Clear, colourless solution. |

**PRESENTATION**:

CYKLOKAPRON Tablets in plastic containers of 24 and 100.

CYKLOKAPRON Ampoules of 5 ml in packs of 5.

**STORAGE INSTRUCTIONS**:

Store at or below 25 °C. Protect from light. Keep out of reach of children.

**REGISTRATION NUMBER**:

CYKLOKAPRON® T 500 Tablets: H/8.1/807

CYKLOKAPRON® I V 500 Injection: H/8.1/806

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton

2196

South Africa

**DATE OF PUBLICATION OF THIS PACKAGE INSERT**:

20 December 1999

**BOTSWANA:** S2

CYKLOKAPRON T 500: Reg. No.: B9300420

CYKLOKAPRON IV 500: Reg. No.: B9300425

**NAMIBIA:** S2

CYKLOKAPRON T 500: Reg. No.: 90/8.1/001298

CYKLOKAPRON IV 500: Reg. No.: 90/8.1/001297

**ZIMBABWE:** PP

CYKLOKAPRON T 500: Reg. No.: 75/10.4/0575

CYKLOKAPRON IV 500: Reg. No.: 75/10.4/574