

Xamic®

Tranexamic Acid

COMPOSITION:

Each capsule contains 500 mg tranexamic acid B. P.
Each ampoule contains 500 mg/5ml tranexamic acid B. P.

DESCRIPTION:

Xamic® is a preparation of tranexamic acid. It is a substance endowed with a strong antifibrinolytic action and both in - vivo and in-vitro it has proved to be from 5 to 10 times more active than aminocaproic acid, depending on the test. The antihemorrhagic action of tranexamic acid is essentially due to an inhibition of the plasminogen activation of both exogenous activators like streptokinase and endogenous ones like urokinase and the plasminogen tissue activator. This fact is particularly important for the clinical use of **Xamic®**, because it ensures an antihemorrhagic activity with an antifibrinolytic mechanism under a variety of conditions. The acute toxicity of **Xamic®** is extremely low and chronic toxicity almost non-existent.

Xamic® is well absorbed by oral route and the effect is already seen 15-30 minutes after administration.

It is excreted mainly by renal route but more slowly than aminocaproic acid.

These features make the **Xamic®** effect more lasting than that of aminocaproic acid. Considerably lower single doses of **Xamic®** can thus be administered at greater intervals without the drug plasma levels dropping to inefficient levels of antifibrinolytic activity between one dose and the other.

Xamic® at therapeutic doses does not interfere with clotting processes and even a prolonged administration has not been seen to be accompanied by any tendency to thrombophilia.

INDICATIONS:

In medicine

Prophylaxis and therapy of hemophthoes, digestive hemorrhages, hemorrhagic syndromes in leukaemia, cirrhosis and hemophilia, thrombocytopoenic purpura, accidents during thrombolytic therapy and transfusion.

In surgery

Prophylaxis and antihemorrhagic therapy during operations of any type and nature and particularly in pulmonary, cardiovascular and abdominal surgery and post-operative and traumatic shock.

In urology

Prophylaxis and antihemorrhagic therapy of prostatic, vesical and renal surgery. Hematurias.

In obstetrics

Prophylaxis and therapy of post-partum and puerperium hemorrhages, hemorrhagic metropathies, functional menometrorrhagias, apparently primitive or symptomatic menorrhagias of diffuse hemorrhagic syndrome.

Primitive hyperfibrinolysis (abruptio placentae, premature placenta detachment).

In otorhinolaryngology

Prophylaxis and antihemorrhagic therapy during tonsillectomy, specialist surgery generally, epistaxis.

In stomatology

Prophylaxis and antihemorrhagic therapy during maxillofacial operations, tooth extractions.

DOSAGE AND ADMINISTRATION:

Adults: For prophylaxis the mean recommended daily doses are 0.5-1g orally, 500 mg by parenteral (intravenous or intramuscular) route, except in cases of administration of different dosages.

For therapy of hemorrhagic manifestations, oral dose increases to 1-3g given in divided doses: in cases of particular seriousness and urgency, begin by injecting an ampoule slowly by intravenous route, and administer the necessary subsequent doses orally.

Children: For prophylaxis, for every kg of body weight from 5 to 10 mg are administered daily orally in divided doses, for therapeutic purposes the oral doses are doubled (from 10 to 20 mg/kg), while the intravenous and intramuscular treatment is begun with 10mg/kg (=0.5 ml every 5 kg) by slow intravenous route, continuing the oral administration up to the required dose.

Where it is more convenient (e.g. in small babies) the ampoules, diluted in a little sweetened water, may be orally administered instead of the capsule.

WARNINGS:

Xamic® should be used in cases where there is hyperfibrinolysis. The prophylactic treatment must begin 24 hours before the operation and continue until 3-4 days after it.

The therapy of hemorrhages must be prolonged for at least 24 hours after manifestations have disappeared.

In hematuria, especially when this is not accompanied by any other hemorrhagic manifestations, reduce the doses to prevent formation of clots in the urinary tract.

Xamic® must not be used in serious renal insufficiency or anuric syndromes, and must only be used with caution in less serious renal dysfunctions.

The administration of the product requires particular care in cardiopathic and hepatopathic subjects. Since the transplacental passage of the drug and its possible effects on the foetus are unknown, **Xamic®** should not be administered during known or presumed pregnancy.

SIDE EFFECTS:

Xamic® is generally well tolerated; there may be infrequent cases of sense of fatigue, conjunctival irritation, nasal blockage, itching, skin reddening, exanthems.

After oral administration there may be sign of nausea, diarrhoea, gastric pyrosis.

There are rare case of postural hypotension.

In the case of hypersensitivity to tranexamic acid, avoid or suspend treatment and start a suitable therapy.

CONTRAINDICATIONS:

Known individual hypersensitivity to the product. Thromboembolic disease, arterial and venous thrombosis. Endocavitary hemorrhages. Serious kidney failure.

STORAGE CONDITION:

Store in a cool (below 30° c) and dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED:

Xamic® capsule : Each box contains 2 x 10's capsules in blister pack.

Xamic® injection : Each box contains 1 x 5's ampoules.

® Trade Mark

Manufactured by



Renata Limited

Mirpur, Dhaka, Bangladesh