120 mm

180 mm

BRINO® Capsules / Injection

(Tranexamic Acid)

COMPOSITION:

BRINO® 250mg Capsules:
Each capsule contains:
Tranexamic Acid BP 250mg

BRINO® 250mg/5ml Injection:
Each 5ml contains:
Tranexamic Acid BP 250mg

BRINO® 500mg Capsules:
Each capsule contains:
Tranexamic Acid BP 500mg

BRINO® 500mg/5ml Injection:
Each 5ml contains:
Tranexamic Acid BP 500mg

CLINICAL PHARMACOLOGY:
Tranexamic acid produces an antifibrinolytic effect by competitively inhibiting the activation of plasminogen to plasmin. It is also a weak noncompetitive inhibitor of plasmin. These properties make possible its clinical use as an antifibrinolytic in the treatment of both general and local fibrinolytic hemorrhages

PHARMACOKINETICS:
Tranexamic acid is absorbed from the gastrointestinal tract with peak plasma concentrations occuring after about 3 hours. Bioavailability is about 30 to 50%. Tranexamic acid is widely distributed throughout the body and has very low protein binding. It diffuses across the placenta and is distributed into breast milk. Tranexamic acid has a plasma elimination half life of about 2 hours. It is excreted in the urine mainly as unchanged drug

INDICATIONS:
1. Treatment of excessive bleeding resulting from systemic or local hyperfibrinolysis:
   - Epistaxis
   - Hyphaema
   - Menorrhagia
2. Prophylaxis in patients with coagulopathy undergoing surgical procedures
3. Hereditary angioneurotic oedema

CONTRAINDICATIONS:
Tranexamic Acid Capsule & Injection should not be administered to:

Patients with a history or risk of thrombosis should not be given tranexamic acid, unless at the same time it is possible to give treatment with anticoagulants

Tranexamic acid should not be given to patients with acquired disturbances of color vision. If disturbances of color vision arise during the course of treatment the administration of the product should be discontinued

The risk of thrombotic and thromboembolic events may increase further when hormonal contraceptives are administered with BRINO® (Tranexamic acid)

Patients with active thromboembolic disease, such as deep vein thrombosis, pulmonary embolism and cerebral thrombosis

Patients with subarachnoid haemorrhage: The limited clinical experience shows that a reduced risk for re-bleeding is offset by an increase in the rate of cerebral ischaemia

PRECAUTIONS:
Care should be taken in cases of renal insufficiency due to the risk of accumulation and where there is pronounced haematuria from the upper urinary tract, since in isolated cases obstacles to passage have been observed in the tract

SIDE EFFECTS:
Gastrointestinal symptoms (nausea, vomitting, and diarrhea) occur but disappear when the dose is reduced. Isolated cases of dizziness or reduced blood pressure have been reported. Allergic skin reactions have been reported less commonly

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

DOSAGE & ADMINISTRATION:
BRINO® 250 & 500mg Capsules
The usual dose for adults is 250 to 500mg 3 to 4 times daily, depending on the severity of symptoms & age

BRINO® Injection
Adult Dose:
Daily dose is 250 to 500mg I/V or I/M in 1 to 2 times during and after operation. If required, then 500 to 1000mg at a time is given intravenously or 500 to 2500mg is given by intravenous drip infusion

BRINO® 250mg/5ml Injection
Adult dose - 1 to 2 ampoules (5 to 10ml) is recommended in divided into 1 to 2 times I/V or I/M during or after operation. If required, 2 to 10 ampoules (10 to 50ml) at a time is given intravenously by drip infusion

BRINO® 500mg/5ml Injection
Adult dose - 2.5 to 5ml divided into 1 to 2 times daily I/V or I/M during or after operation. If required, 5 to 10ml at a time is given intravenously or 5 to 25ml at a time is given intravenously by drip infusion

Children may be given doses of 25mg/kg by mouth or 10mg/kg intravenously, usually 2 or 3 times daily, depending on the indication

Reduced doses are recommended for patients with renal impairment. Solutions of tranexamic acid have been applied topically, for example as a bladder irrigation or mouth wash

OR
As directed by the physician

PRESENTATION:
BRINO® 250mg capsules in a pack of 20's
BRINO® 500mg capsules in a pack of 20's
BRINO® 250mg/5ml injection in a pack of 10's
BRINO® 500mg/5ml injection in a pack of 10's

STABILITY:
See expiry on the pack

INSTRUCTION:
Do not chew or crush capsule contents
The capsule should be swallowed whole with water
Keep out of reach of children
Avoid exposure to heat, light, humidity and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

برائینو کیپسول/انجکشن

(ٹرانکزامک ایسڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات: کیپسول چبائے بغیر پانی سے نگل لیں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل

پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

P000853/S
R.N-07/HA/06/15/Pampac