רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

TRANEX INJECTION

חברת טק-או-פארם ליברה בע"מ מבקשת להודיע כי העלון לרופא עודכן.
מכתב זה מציין רק את העדכונים העיקריים המהווים החמרות. בוצעו שינויים נוספים קלים בעלון שאינם מהווים החמרה.

הרכב התכשיר- מרכיב פעיל:
TRANEXAMIC ACID 100MG/ML

התוויה מאושרת:

Prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one
year.
Specific indications include:
- Haemorrhage caused by general or local fibrinolysis such as:
* Menorrhagia and metrorrhagia
* Gastrointestinal bleeding
* Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear Nose Throat surgery (adenoidectomy, tonsillectomy, dental extractions)
- Gynaecological surgery or disorders of obstetric origin
- Thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery
- Management of haemorrhage due to the administration of a fibrinolytic agent

צורת המתן: IV

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם
מודפסים ע"י פנייה לבעל הרישום: חברת טק-או-פארם ליברה בע"מ, ת.ד 39065, תל אביב.

בכבוד רב,
חברת טק-או-פארם ליברה בע"מ

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ההחמרות בעלון לרופא נעשו בסעיפים הבאים:

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
- Acute venous or arterial thrombosis (see section 4.4);
- Fibrinolytic conditions following consumption coagulopathy except in those with predominant activation of the fibrinolytic system with acute severe bleeding (see section 4.4);
- Severe renal impairment (risk of accumulation);
- History of convulsions;
- Intrathecal, epidural, intraventricular injection and intracerebral application (risk of cerebral oedema and convulsions and death).

4.4 Special warnings and precautions for use

The indications and method of administration indicated above should be followed strictly:

- Intravenous injections should be given very slowly
- Tranexamic acid should not be administered by the intramuscular route.

Risk of medication errors due to incorrect route of administration

Tranex Injection is for intravenous use only. Intrathecal, epidural, intraventricular and intracerebral use of Tranex Injection is contraindicated (see section 4.3). Serious adverse reactions including fatal events have been reported when tranexamic acid was inadvertently administered intrathecally. These include severe back, gluteal and lower limb pain, myoclonus and generalized seizures, and cardiac arrhythmias.

Care should be exercised to ensure the correct route of administration of Tranex Injection. Healthcare professionals should be aware of the potential for confusion of Tranex Injection with other injectables which could result in inadvertent intrathecal administration of Tranex Injection. This includes in particular intrathecally administered injectables that may be used during the same procedure as Tranex Injection.

Syringes containing Tranex Injection should be clearly labelled with the intravenous route of administration.

4.8 undesirable effects

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MedDRA System Organ Class	Frequency	Undesirable Effects
Skin and subcutaneous tissues disorders	Uncommon Not known	- Dermatitis allergic -Fixed drug eruption
Gastrointestinal disorders	Common	- Diarrhoea - Vomiting

MedDRA System Organ Class	Frequency	Undesirable Effects
		- Nausea
Nervous system disorders	Not known	- Dizziness, Convulsions particularly in case of misuse (refer to sections 4.3 and 4.4)
Eye disorders	Not known	- Visual disturbances including impaired colour vision
Vascular disorders	Not known	- Malaise with hypotension, with or without loss of consciousness (generally following a too fast intravenous injection, exceptionally after oral administration) - Arterial or venous thrombosis at any sites
Immune system disorders	Not known	- Hypersensitivity reactions including anaphylaxis
Renal and urinary disorders	Not known	- Acute renal cortical necrosis

6.6 Special precautions for disposal and other handling

Healthcare professionals are strongly advised to label the Tranex Injection syringes during the withdrawal of the product from the ampoules for clear identification and proper route of administration, to help prevent inadvertent medication errors during administration to the patient. For single use only. Any portion of unused ampoule should be discarded.