PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

11th December 2025

Tranexamic acid intravenous formulations – Serious including fatal adverse reactions due to inadvertent intrathecal administration

Dear Healthcare professional,

Pfizer Healthcare Ireland Unlimited Company and Ibigen S.r.l. in agreement with the Europe Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- **Tranexamic acid injectable formulation is authorised for intravenous use only. Intrathecal, epidural, intraventricular and intracerebral use of tranexamic acid injectable is contraindicated.**
- **Extreme caution should be taken when storing, handling and administering intravenous formulations of tranexamic acid to ensure the correct route of administration. This includes clearly labelling syringes containing tranexamic acid for intravenous use only and storing tranexamic acid injectables separately from injectable local anaesthetics.**
- **Serious, including fatal, adverse reactions have been reported after inadvertent intrathecal administration due to mix-ups, mostly with injectable local anaesthetics.**

Background on the safety concern

Tranexamic acid is an antifibrinolytic indicated in adults and children from one year of age in prevention and treatment of haemorrhages due to general or local fibrinolysis. 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.

Tranexamic acid injectable is authorised for intravenous use only. It **must not** be administered intrathecally, epidurally, by intraventricular injection or by intracerebral application. Cases of medication errors have been identified, including cases reported in the EU, where tranexamic acid injection was inadvertently administered intrathecally or epidurally. Most of these cases involved mix-ups of vials or ampoules resulting in erroneous administration of tranexamic acid instead of the intended injectable local anaesthetic (e.g. bupivacaine, levobupivacaine, prilocaine).

When administered intrathecally, serious patient harms were reported including prolonged hospitalisation and death. Serious adverse reactions following inadvertent intrathecal administration included severe back, gluteal and lower limb pain, myoclonus and generalised seizures and cardiac arrhythmias.

Healthcare professionals should take extreme care to ensure correct route of administration of tranexamic acid. Healthcare professionals should be aware of the potential for a mix-up between tranexamic acid and other injectable products which could result in inadvertent administration of tranexamic acid by an incorrect route. In particular, this includes intrathecally administered injectable products that may be used during the same procedure as tranexamic acid.

In order to reduce the risk of fatal medication errors due to incorrect route of administration, syringes containing tranexamic acid should be clearly labelled for identification and correct route of administration.

It is also advised to store tranexamic acid injectables separately from injectable local anaesthetics to prevent accidental mix-up.

The product information of injectable tranexamic acid products, including the outer packaging, will be updated to strengthen the warnings that tranexamic acid injection should only be administered intravenously.

Call for reporting

Healthcare professionals should report any suspected adverse reactions or medication errors associated with the use of tranexamic acid via HPRA Pharmacovigilance, website: www.hpra.ie

Suspected adverse drug reactions may also be reported to the marketing authorization holders, see contact details below.

Company contact point

These materials are being sent to you on behalf of the group of companies listed below, who are Marketing Authorisation holders for medicines containing tranexamic acid. If you require additional information, please contact the medical information services of the individual company.

Company	Adverse reaction reporting details
Pfizer Healthcare Ireland Unlimited Company	Pfizer Medical Information at www.pfizermedicalinformation.ie, Telephone: 1 800 633 363 or, www.pfizersafetyreporting.com
Ibigen S.r.l.	Bowmed Ibisqus Limited (on behalf of Ibigen S.r.l.) Email: medinfo@bowmed.com Tel: (+44) 01483 212151 Website: www.bowmed.com

Yours sincerely,

Company	Signed
Pfizer Healthcare Ireland Unlimited Company	 **Pádraig J. Moran** Country Medical Lead, Pfizer Healthcare Ireland UC.
Bowmed Ibisqus Limited (on behalf of Ibigen S.r.l.)	 **Louise Crosbie** Technical and Quality Manager, RPi/RP Bowmed Ibisqus Limited