Injectable tranexamic acid: serious adverse reactions when inadvertently given intrathecally

07/05/2026 | Circular Number P05/2026

Information on injectable tranexamic acid

- 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.

In Malta the following products are authorised through national licensing procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Tranexamic Acid 100 milligram(s)/millilitre	Tranexamic Acid 100 mg/ml solution for injection/Infusion (5ml ampoule)	Solution for injection/infusion	POM	MA965/00701	Ibigen S.r.L
Tranexamic Acid 100 milligram(s)/millilitre	TRANEXAMIC ACID 100 milligram(s)/millilitre	Solution for injection/infusion	POM	MA965/00702	Ibigen S.r.L
Tranexamic Acid 100 milligram(s)/millilitre	Medsamic 100 mg/ml solution for injection (5ml)	Solution for injection/infusion	POM	MA032/14601	Medochemie Limited

Tranexamic Acid 100 milligram(s)/millilitre	Medsamic 100 mg/ml solution for injection (10ml)	Solution for injection/infusion	POM	MA032/14602	Medochemie Limited
Tranexamic Acid 100 milligram(s)/millilitre	Tafixyl 100 mg/ml solution for injection	Solution for injection/infusion	POM	AA1253/00103	Pharma Bavaria Internacional (PBI) Portugal Unipessoal Lda
Tranexamic Acid 100 milligram(s)/millilitre	Pilexam solution for injection 100 mg/ml	Solution for injection/infusion	POM	AA242/03001	Pharmabart Limited
Tranexamic Acid 100 milligram(s)/millilitre	Exacyl 100 mg/ml solution for injection	Solution for injection/infusion	POM	AA770/22601	JV Healthcare Limited

Information from the EMA about the safety concern

- Tranexamic acid injectable is authorised for **intravenous use only**. It must not be administered intrathecally, epidurally, by intraventricular injection or by intracerebral application.
- PRAC reviewed cases of medication errors, including reports from across the EU, where injectable tranexamic acid was mistakenly given either intrathecally or epidurally due to mix-ups with other medicines, mostly local anaesthetics.
- Intrathecal use resulted in serious side effects, including severe pain in the back, buttock and legs, seizures and cardiac arrhythmias (abnormal or irregular heartbeat), and in some cases death.
- Risk of medication errors with intravenous formulations of tranexamic acid are associated with incorrect route of product administration.
- The product information of intravenous formulations of tranexamic acid should inform healthcare professionals and raise awareness of the nature of medication errors that have occurred in the post-marketing setting with tranexamic acid and the resulting harms particularly in relation to intrathecal administration.
- Recommendations on measures to minimise the risk of incorrect route of product administration should be provided to healthcare professionals.
- There is also more limited evidence of inadvertent epidural administration. Given the potential for serious morbidity and mortality when non-epidural medicines are administered by this route, it is also considered that
- 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).

- The product information of injectable tranexamic acid medicines, including the outer packaging, will be updated to strengthen the warnings that these medicines must only be given intravenously:
    - A contraindication is added to the existing contraindications included in the product information regarding epidural administration.
    - Updates to the particulars of the outer packaging are carried out to reinforce information on the correct route of administration.
- A causal relationship between tranexamic acid and **acute renal cortical necrosis** is possible. The PRAC concluded that the product information of products containing tranexamic acid are amended accordingly.
- A close temporal relationship between tranexamic acid and **fixed drug eruption** is possible. The PRAC concluded that the product information of products containing tranexamic acid are amended accordingly.

For more information visit the European Medicines Agency's website at www.ema.europa.eu and the SmPC or tranexamic acid.

In Malta

For Healthcare Professionals

- Healthcare professionals should take measures to prevent potential mix-ups between injectable tranexamic acid and other injectable medicines, especially those given intrathecally, that may be used during the same procedure, such as local anaesthetics.
- To reduce the risk of medication errors, syringes containing tranexamic acid should be clearly labelled for intravenous use only.
- It is also advised to store injectable tranexamic acid separately from local anaesthetics.
- Healthcare professionals should report any signs and symptoms related to **acute renal cortical necrosis** and **fixed drug eruption** when a patient is taking tranexamic acid.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on **Injectable tranexamic acid**. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences

Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Archived Safety Circulars
Archived Direct Healthcare Professional Communications
Archived Risk Minimisation Measures

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Malta Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000