If undelivered please return to Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta

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10th December 2025

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

Dear Healthcare professional,

Medochemie Limited, Pharma Bavaria Internacional (PBI) Portugal Unipessoal Lda, Pharmabart Limited and JV Healthcare Limited in agreement with the European Medicines Agency and the Malta Medicines Authority 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[1] 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).

[1] Tranexamic Acid SmPC: antifibrinolytic-medicines-article-31-referral-annex-iii-tranexamic-acid_en.pdf

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 are asked to report any suspected adverse drug reactions, in accordance with the national spontaneous reporting system and include batch/Lot number if available, by using the Malta Medicines Authority ADR reporting form available online at http://medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Healthcare Professionals may also report any adverse events associated with the use of Tranexamic Acid intravenous formulations to:

Company contact points:

Company	Product Name	Email	Contact
Medochemie Limited	Medsamic 100 mg/ml solution for injection (5ml) Medsamic 100 mg/ml solution for injection (10ml)	annalisa@cherubino.com.mt pharmacovigilance@cherubino.com.mt	(+356) 22588715
Pharma Bavaria Internacional (PBI) Portugal Unipessoal Lda.	Tafixyl 100 mg/ml solution for injection	pharmacovigilancemt@mint.com.mt	(+356) 2093 9800
Pharmabart Limited	Pilexam solution for injection 100 mg/ml	rp@pharmabart.eu	(+356) 21436348 (+356) 21436349
JV Healthcare Limited	Exacyl 100 mg/ml solution for injection	alexandra.grima@jvpharma.eu	(+356) 21437551

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Medochemie Limited, Pharma Bavaria Internacional (PBI) Portugal Unipessoal Lda, Pharmabart Limited and JV Healthcare Limited

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.