## Direct Healthcare Professional Communication

<Date>

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

Dear Healthcare professional,

<Name of marketing authorisation holder> in agreement with the European Medicines Agency and the <National Competent 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 include <to be agreed at national level>

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.

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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 in accordance with the national spontaneous reporting system.

## *Company contact point*

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

## ***Annexes** (if applicable)*

<Link/reference to other available relevant information, such as information on the website of a competent authority>

## Communication Plan for Direct Healthcare Professional Communication

| DHPC COMMUNICATION PLAN | |
|---|---|
| **Medicinal product(s)/active substance(s)** | Tranexamic acid, intravenous formulations |
| **Marketing authorisation holder(s)** | *In cases where the DHPC concerns several marketing authorisation holders of the same active substance or is part of a class review, it is strongly encouraged that a single consistent message is sent to healthcare professionals in each EU Member State.*<br><br>*All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter circulated in each Member State should cover all active substance-containing products authorised in that Member State.*<br><br>*It is encouraged that the originator marketing authorisation holder (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.* |
| **Safety concern and purpose of the communication** | Tranexamic acid intravenous formulations – Serious including fatal adverse reactions due to inadvertent intrathecal administration |
| **DHPC recipients** | Anaesthetists, Hospital pharmacists<br><br>The target group for the distribution of the DHPC should be further agreed at the national level, with the relevant National Competent Authorities |
| **Member States where the DHPC will be distributed** | Member States where tranexamic acid intravenous formulations are marketed. |

| Timetable | Date |
|---|---|
| **DHPC and communication plan (in English) agreed by PRAC** | 30 October 2025 |
| **DHPC and communication plan (in English) agreed by CMDh** | 13 November 2025 |
| **Submission of translated DHPCs to the national competent authorities for review** | 27 November 2025 |
| **Agreement of translations by national competent authorities** | 4 December 2025 |
| **Dissemination of DHPC** | 11 December 2025 |