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To:

Pharmacist Incharge, Armed Forces Hospital (AT Khoudh & Salalah)
Director of Pharmaceutical Care, Royal Hospital
Director of Pharmaceutical Care, Khoula Hospital
Pharmacist Incharge, Al Nahda Hospital
Director of Pharmaceutical Care, DGHS, Muscat Governorate
Director of Pharmaceutical Care, DGHS, Al Dakhliya Governorate
Director of Pharmaceutical Care, DGHS, South Batinah Governorate
Director of Pharmaceutical Care, DGHS, North Batinah Governorate
Director of Pharmaceutical Care, DGHS, Al Dhahira Governorate
Director of Pharmaceutical Care, DGHS, North Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, South Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, Musandam Governorate
Director of Pharmaceutical Care, DGHS, Dhofar Governorate
Director of Pharmaceutical Care, DGHS, Al Wusta Governorate
Director of Pharmaceutical Care, DGHS, Buraimi Governorate
Director of Pharmaceutical Care, DGMS
Pharmacist Incharge, Al Massarah Hospital
HOD, Pharmacy Department, Sultan Qaboos University Hospital
Pharmacist Incharge, Royal Oman Police
Pharmacist Incharge, The Diwan
Pharmacist Incharge, The Sultan's Special Force
Pharmacist Incharge, Internal Security Services
Pharmacist Incharge, Petroleum Development of Oman
Pharmacist Incharge, LNG Oman

After Compliments,

Kindly find attached our Circular No 211 dated 23 /11/2025 regarding Update to Health Care Professionals About Risk of Inadvertent Intrathecal (Spinal) Administration of Tranexamic Acid Injection.

Copy to:

- Director General, DSC
-  Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Director Medical Device Control, DSC
-  Head of Central Drug Information
- Head of Cordin. & FU



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Circular No. 20 /2025

2-06-1447 H
23-11-2025

Subject: Update to Health Care Professionals About Risk of Inadvertent Intrathecal (Spinal) Administration of Tranexamic Acid Injection

The Drug Safety Center (DSC) would like to share a new safety information published by American Food and Drug Authorization (FDA) website regarding Update to Health Care Professionals About Risk of Inadvertent Intrathecal (Spinal) Administration of Tranexamic Acid Injection.

American Food and Drug Authorization (FDA) is requiring labeling changes to strengthen the warnings that tranexamic acid injection should be administered only intravenously (into the vein). Tranexamic acid injection products are not to be administered intrathecally (into the spine) or as an epidural injection. FDA is taking this action after having identified and evaluated medication error cases of inadvertent neuraxial (intrathecal or epidural) administration of tranexamic acid. In these cases, tranexamic acid was erroneously administered neuraxially instead of the intended local anesthetic (e.g., bupivacaine, lidocaine, mepivacaine, and ropivacaine), which resulted in serious patient outcomes, including prolonged hospitalization and death.

Tranexamic acid injection is indicated for short-term use (2 to 8 days) in patients with hemophilia to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction. Health care professionals should only administer tranexamic acid injection by the intravenous route.

Health care professionals should consider the following steps to minimize the risk of inadvertent neuraxial administration of tranexamic acid injection:

Storage

- Do not store tranexamic acid injection vials or ampules near local anesthetics or in kits containing local anesthetics intended for spinal or epidural anesthesia.
- Store medication vials in a way that makes the labels visible to avoid reliance on identifying drugs by the vial cap color.
- Use barcode scanning (if available) when stocking medication cabinets to ensure the correct medication is placed in the appropriate storage bin.
- Store tranexamic acid injection vials and ampules in separate carts outside the operating room or in locked bins that require barcode scanning to remove from the bin.



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Administration

- Use commercially available or pharmacy-prepared intravenous infusion bags of tranexamic acid, when possible, to minimize confusion with local anesthetics supplied in vials or ampules.
- Use barcode scanning (if available) and always check the container label to ensure the correct product is selected and administered.
- If withdrawing tranexamic acid injection from a vial or ampule, promptly label each syringe when it is prepared unless it is immediately administered.
- If using pre-packaged spinal or epidural kits, carefully inspect the container labels of medications included in the kit to verify the intended medication before use.

Additional Recommendations for Health Care Facilities

- Add a prominent "contains tranexamic acid" auxiliary warning label to all vials and ampules that contain tranexamic acid injection.
- Add tranexamic acid injection to internal high-alert medication lists and develop procedures and policies to ensure safe use and minimize the risk of mix-up with other medications.

Call to report:

Tranexamic acid injection is registered in Oman, healthcare professionals, patients, and caregivers are requested to submit adverse drug reaction reports to the pharmacovigilance and Drug Information Department in the Drug Safety Center (DSC).


Ph. Ibrahim Nasser Al Rashdi
Director General



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