File No. PMDSM-14011(27)/15/2026-eoffice (Comp. No. 35831)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Post Marketing Drugs Safety Monitoring Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Date: 21 JUL 2026

To,

All State/UT Licensing Authorities.

Subject: - Tranexamic Acid related "Back Pain" - Recommendations for the change in Prescribing Information Leaflets (PILs)-regarding.

Sir,

The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), Ghaziabad, has forwarded recommendations vide their letter dated 24th November 2025 arising from the assessment of Adverse Drug Reaction (ADR) reports pertaining to **Tranexamic Acid** formulations, which was discussed in 27th Signal Review Panel dated 11th September, 2025. In the meeting, the PvPI has evaluated the Patient Population Incidence - Adverse Drug Reactions (PPIs-ADR) based on Individual Case Study Reports (ICSR) and made recommendation to CDSCO to take necessary measures to incorporate ***"Back Pain"*** as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the ***Tranexamic Acid*** based medical products marketed in the country.

The aforementioned recommendations of NCC-PvPI were subsequently reviewed by the Subject Expert Committee (Haematology) during its meeting held on 16.04.2026 at CDSCO-HQ, New Delhi. After detailed deliberations, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to incorporate **'Back Pain'** associated with **Tranexamic Acid** as ADR in the corresponding Prescribing Information Leaflet (PIL) of the drug.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of ***Tranexamic Acid*** formulations under

your jurisdiction to mention ***"Back Pain"*** as an adverse drug reaction in the Package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy for information & follow-up: -

1. All Zonal / Sub Zonal Offices of CDSCO.

Copy to:-

2. PvPI, Indian Pharmacopeia Commission, Ghaziabad.
3. PPS to DCG(I).
4. Website of CDSCO.