

File No. PSUR-13011(14)/1/2025-eoffice-Part (2)
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

Dated: 17 FEB 2026

To,

All State/UT Licensing Authorities

Subject:- Doxycycline related CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, and Dizziness) - 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 arising from the assessment of Adverse Drug Reaction (ADR) reports pertaining to Doxycycline formulations, which was discussed in 26th Signal Review Panel dated 24th March, 2025 meeting. 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 "**CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, and Dizziness)**" as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the Doxycycline based medical products marketed in the country.

The aforementioned recommendations of NCC-PvPI were subsequently reviewed by the Subject Expert Committee (SEC) on Antimicrobial & Ant parasitic during its meeting held on 08.01.2026 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 CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, and Dizziness) with Doxycycline as

ADR in the corresponding Prescribing Information Leaflet (PIL) of the drug. Further, committee also recommended to include above side-effects in the caution section of the PIL.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Doxycycline formulations under your jurisdiction to mention "**CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, and Dizziness)**" as an adverse drug reaction in the caution section of Package insert/Promotional Literature of the drug.

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

Yours faithfully,


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

Copy for information & follow-up: -

1. All Zonal / Sub Zonal Offices of CDSCO.

Copy to:-

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