

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: 1 / FEB 2026

To,

All State/UT Licensing Authorities

**Subject:- Carbimazole related agranulocytosis - 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 Carbimazole formulations, which was discussed in 26th Signal Review Panel dated 24th March, 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 "**agranulocytosis**" as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the Carbimazole based medical products marketed in the country.

The aforementioned recommendations of NCC-PvPI were subsequently reviewed by the Subject Expert Committee (SEC) on Endocrinology and Metabolism during its meeting held on 06.01.2026 at CDSCO-HQ, New Delhi. After detailed deliberations, the committee recommended After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to incorporate agranulocytosis associated with Carbimazole 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 Carbimazole formulations under your jurisdiction to mention "**agranulocytosis**" as an adverse drug reaction in the Prescribing Information Leaflet (PIL) /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.