

F. No. 12-01/18-DC (Pt-337)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi,

Date: 14 JUN 2022

To

All State/UT Drugs Controllers,

Sub: Prescribing Information Leaflet change for "Tramadol" marketed in the country- Reg.

Sir,

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC, Ghaziabad has forwarded their recommendation based on ADR reports on Tramadol which was discussed by them in the 18th Signal Review Panel (SRP) under the programme meeting held on 12th March, 2021 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, PvPI has evaluated the reported ADRs for Tramadol on the basis of Individual Case Study Reports (ICSRs) and recommended CDSCO to take necessary steps to incorporate **Urinary Retention** as an adverse drug reaction in the Prescribing Information Leaflet (PIL) of Tramadol marketed in the country.

Subsequently, PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Analgesic & Rheumatology) meeting held on 19.05.2022 at CDSCO (HQ), New Delhi.

After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of the drug to include **Tramadol induced Urinary Retention** as an adverse drug reaction in the package insert of the drug as suggested by PvPI.

The recommendation of the SEC has been considered by this office.

Accordingly, you are requested to direct the manufacturers of Tramadol under your jurisdiction to incorporate **Tramadol induced Urinary Retention** 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. V.G. Somani
Drugs Controller General (India)

1. Copy for information & follow-up:

All Zonal / Sub Zonal offices of CDSCO.

2. Copy for information:

JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.