

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

FDA Bhawan, Kotla Road,
New Delhi.

Dated: 24-07-2019

To,

All State/UT Drugs Controllers,

Sir/Madam,

Sub: Diclofenac associated Nicolau's Syndrome -Reg.

The drug Diclofenac is approved by CDSCO and marketed in the country in various dosage form.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has sent their recommendation based on ADR reports on certain medicinal products including Diclofenac, which were discussed by them in the 12th Signal Review Panel (SRP) under the programme meeting held on 27th March, 2018, with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Diclofenac -ADR on the basis of Individual Case Study Reports (ICSRs) and recommended CDSCO to take necessary steps to incorporate **Nicolau's Syndrome as an adverse drug reaction** in to the prescribing information leaflet (PIL) of the drug Diclofenac injection marketed in the country.

Subsequently, the PvPI recommendation was deliberated in the Subject Expert Committee (SEC-Analgesic & Rheumatology) meeting held on 19.06.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee recommended that Nicolau's Syndrome shall be incorporated in the package insert of the drug Diclofenac injection as suggested by PvPI.

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

Accordingly, you are requested to direct the manufacturers of Diclofenac injection under your jurisdiction to mention Nicolau's Syndrome 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. S. Eswara Reddy
Drugs Controller General (India)

1. Copy for information & follow-up: -
All Zonal / Sub Zonal Offices of CDSCO.

2. Copy for information to: -
JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.