

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-110002

Dated: **09 MAR 2021**

To,

All State/UT Drugs Controllers,

Sub: Incorporation of Benidipine associated Photosensitivity reaction in the prescribing Information Leaflet - Reg.

Sir/Madam,

Benidipine are approved by CDSCO and marketed in the country in various dosage forms.

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 certain medicinal products including **Benidipine** which were discussed by them in the 16th Signal Review Panel (SRP) under the programme meeting held on 27.12.2019 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 Benidipine -ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate Benidipine associated **Photosensitivity reaction** as an adverse drug reaction in to the prescribing information leaflet (PIL) of the drug **Benidipine** formulations marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Cardiovascular & Renal) meeting held on 04.02.2021 at CDSCO

HQR, New Delhi. After detailed deliberation, the Committee has recommended that **Photosensitivity reaction** should be incorporated in the package insert of the drug **Benidipine** as suggested by PvPI.

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

Accordingly, you are requested to direct the manufacturers of **Benidipine** formulations under your jurisdiction to mention **Photosensitivity reaction** 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 to: -

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