

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: 13 MAY 2022

To,

All State/UT Drugs Controllers,

Sir,

Sub: Prescribing Information Leaflet change for Pulmonary surfactant associated Pulmonary Haemorrhage of Pulmonary surfactant marketed in India-Reg.

Various Pulmonary surfactants are approved by CDSCO and marketed in the country.

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 Proton pump inhibitors which were discussed by them in the 6th Signal Review Panel (SRP) under the programme meeting held on 06th Oct, 2015 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 PPIs-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate **Pulmonary Haemorrhage** as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the pulmonary surfactant marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Pulmonary) meeting held on 29.03.2022 at CDSCO HQ, New Delhi.

After detailed deliberation, the Committee has recommended that CDSCO should request the State Drugs Controller to direct the manufactures of the drug to include **surfactant induced Pulmonary Haemorrhage** as adverse drug reaction to the corresponding PIL of the drug.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Pulmonary Surfactant formulations under your jurisdiction to mention **Pulmonary Haemorrhage** 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.