

File. No 12-01/15-DC (Pt.23)
Directorate General of Health Services
Office of Drugs Controller General (India)
(New Drug Division)

FDA Bhawan,
Kotla Road, New Delhi
Dated 12, 05, 2015

To
All State Drugs Controllers

**Subject: Important safety label changes to Carbamazepine containing products -
Regarding.**

Sir,

CDSCO launched a national Pharmacovigilance Programme of India (PvPI) in the year 2010 to monitor the Adverse Drug Reactions (ADRs). At present 150 ADR Monitoring Centers (AMCs) are functioning under National Co-ordination Centre (NCC) to monitor and report ADR across the country.

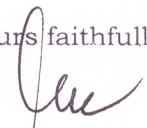
PvPI has received 122 reports of life threatening or fatal skin reactions (Stevens Johnson's Syndrome, Toxic Epidermal Necrolysis) that may have been caused by the use of Carbamazepine formulations in the country. These 122 reports are out of 1882 reports of Carbamazepine induced ADRs from India in VigiBase till 1st Dec, 2014.

The Subject Expert Committee (SEC) - Neurology & Psychiatry in its meeting held on 03.03.2015 examined the prescribing information submitted by some firms which were permitted for marketing the drug in the country and the recommendation of the Signal Review Panel (SRP), PvPI for screening of HLA-B *1502 prior to initiating the carbamazepine treatment because it is a known risk factor for carbamazepine induced Stevens Johnson's Syndrome. It was observed by the Committee that association between Stevens Johnson's Syndrome and HLA-B *1502 are already included in the prescribing information of the mentioned firms. The Committee felt at this stage no additional label warning is required. However, the Committee recommended that all the manufacturers should include the same in the prescribing information and the same should be available on the official website of all the firms manufacturing Carbamazepine in the country.

It is therefore, requested that all the manufacturers licensed for the said product under your jurisdiction should be asked for inclusion of the same in the prescribing information and the same should be available on the official website of all the manufacturers manufacturing Carbamazepine in the country.

Action taken in the matter may please be communicated to the undersigned.

Yours faithfully,



(Dr. G.N. Singh)

Drugs Controller General (India)

Copy forwarded for information and necessary follow up to the Zonal/ Sub Zonal officers of CDSCO.