



P.17019/01/2021-PvPI
Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
(Ministry of Health & Family Welfare, Govt. of India)

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Sector-23, Raj Nagar,
Ghaziabad-201002, U.P.
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Monthly Drug Safety Alerts

The preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database reveals that the following suspected drugs is associated with the ADRs as given below.

Sl. No.	Suspected Drugs	Indication	Adverse Drug Reactions
1.	Clobazam	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome
2.	Baclofen	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.	Encephalopathy
3.	Rosuvastatin & Ticagrelor Interaction	Rosuvastatin: Risk reduction of MI stroke and arterial revascularisation procedure in patients without clinically evident CHD but with multiple risk factors. Ticagrelor: For the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST Elevation Myocardial Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG).	Rhabdomyolysis

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>), through Android Mobile App “**ADR PvPI App**” and **PvPI Helpline No. 1800-180-3024 (Toll Free)**.

