


## Drug Safety Alerts issued by Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India (PvPI) from January - June 2021

The preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database reveals that the following suspected drugs are associated with the ADRs reported by PvPI during January to June 2021 as given below.<sup>1</sup>

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of these ADRs associated with the use of the suspected drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling

S. No.	Suspected Drug	Indication	Adverse Drug Reactions
1.	Fexofenadine	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.	Blurred Vision
2.	Ambroxol	Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.	Fixed Drug Eruption
3.	Cefpodoxime	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome
4.	Clarithromycin	Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	Burning Sensation
5.	Hydroxyzine	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine -mediated pruritus.	Photosensitivity Reaction
6.	Salicylic Acid	For the treatment of acne vulgaris.	Photosensitivity Reaction
7.	Zinc (Acetate/Oxide/Sulphate/ Gluconate)	In treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea
8.	Clobazam	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	DRESS Syndrome
9.	Baclofen	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.	Encephalopathy
10.	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

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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) or through nearby Adverse Drug Reaction Monitoring Centre (AMC).

IPC is a WHO-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services in SEARN.

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## REFERENCE

1. <http://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/416-drug-safety-alerts.html>

