



INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

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Drug Safety Alert

The preliminary analysis of SUSARs from the PvPI database reveals that the following drugs are associated with the risks as given below.

Table

S.No	Suspected Drug	Indication	Adverse Reaction(s)
1	Hepatitis B immune globulin (human)	Active immunisation against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV-positive material.	Encephalopathy
2	Cefotaxime	Infections due to sensitive gram-positive and gram-negative bacteria such as bacteraemia, cellulitis, Intra-abdominal infections, gonorrhoea, bone or joint infections, skin and skin structure infections, urinary tract infections, septicaemias, surgical prophylaxis, endometritis, life threatening resistant/hospital acquired infections, infections in immune-compromised patients, Haemophilus epiglottitis and meningitis.	Anaphylactic Shock.
3	Lacosamide	As an adjunctive treatment of partial onset seizures in patients > 17 years of age.	Red Man Syndrome
4	Dimethyl fumarate	For Relapsing remitting multiple sclerosis.	Osteonecrosis
5	Sodium citrate/Diphenhydramine hydrochloride/Ammonium chloride	For Symptomatic treatment of cough.	Myocardial Infraction

Healthcare professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse reaction(s) while prescribing/consuming above suspected drugs and report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/ Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>) or by PvPI Helpline No. 1800-180-3024.

“Let us join hands with PvPI to ensure patients safety”

ADR Reporting Help line (Toll Free): 1800-180-3024