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PvPI Recommendations to CDSCO for Regulatory Actions

The India specific drug safety signals/drug alerts/others are identified from the reported ADRs by the Signal Review Panel (SRP) of Pharmacovigilance Programme of India (PvPI) and recommended to Central Drugs Standard Control Organisation (CDSCO) for the appropriate regulatory actions as follows:

S.No	Suspected drugs	Adverse drug reactions	Recommendations	Action taken by CDSCO
1	Carbamazepine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	For Drug Safety Label Change – Patient may be screened for HLA-B*1502 prior to initiating the carbamazepine treatment	Issued an order to all MAHs to comply the same
2	Mannitol	Hypokalaemia	To include in Prescribing Information	In process
3	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	To include in Prescribing Information	Issued an order to all MAHs to comply the same
4	Rota Vaccine	Intussusception	To include in Prescribing Information	In process
5	Ranitidine	Cardiac Arrest	To include in Prescribing Information	In process
6	Anti-Rabies Vaccine	Erythema Multiforme	To include in Prescribing Information	In process
7	Pulmonary Surfactant	Pulmonary Haemorrhage	To include in Prescribing Information	In process
8	Ceftriaxone	Stevens Johnson syndrome	To include in Prescribing Information	In process
9	Lamotrigine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	In process
10	Betamethasone	Photosensitivity Reaction	To include in Prescribing Information	In process

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



INDIAN PHARMACOPOEIA COMMISSION

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11	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	In process
12	Cloxacillin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	In process
13	Cefixime	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal	In process
14	Itraconazole	Photosensitivity reaction	To include in Prescribing Information	In process
15	Ibuprofen	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	In process
16	Amoxicillin/Clavulanate Potassium	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	In process
17	Ciprofloxacin	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	To include in Prescribing Information	In process
18	Sodium Valproate	Gum Hyperplasia	To include in Prescribing Information	In process
19	BCG vaccine	Lymphadenopathy	To include in Prescribing Information	In process
20	Docetaxel	Candidiasis	To include in Prescribing Information	In process
21	Furosemide	Dermatitis Lichenoid	Signal	In process
22	Itraconazole	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal	In process
23	Lithium Carbonate	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)	Signal	In process
24	Phenytoin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in Prescribing Information	In process

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