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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 CDSCO for the appropriate regulatory actions as follows:

S.No	Date of recommendation	Suspected drugs	Adverse drug reactions	Regulatory action required
1	08-12- 2014	Carbamazepine	Stevens Johnson syndrome and Toxic Epidermal Necrolysis	For Drug Safety Label Change
2	09-05- 2015	Mannitol	Hypokalaemia	For Drug Safety Label Change
3	09-05- 2015	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	For Drug Safety Label Change
4	09-05- 2015	Rota Vaccine	Intussusception	For Drug Safety Label Change
5	06-10- 2015	Ranitidine	Cardiac Arrest	For Drug Safety Label Change
6	06-10- 2015	Anti-Rabies Vaccine	Erythema Multiforme	For Drug Safety Label Change
7	06-10- 2015	Pulmonary Surfactant	Pulmonary Haemorrhage	For Drug Safety Label Change
8	01-03- 2016	Ceftriaxone	Stevens Johnson syndrome	For Drug Safety Label Change
9	01-03- 2016	Lamotrigine	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	For Drug Safety Label Change
10	01-03- 2016	Betamethasone	Photosensitivity Reaction	For Drug Safety Label Change
11	01-03- 2016	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)	For Drug Safety Label Change
12	01-03- 2016	Cloxacillin	Acute Generalised Exanthematosus Pustulosis (AGEP)	For Drug Safety Label Change
13	08-07- 2016	Cefixime	Acute Generalised Exanthematosus Pustulosis (AGEP)	Signal
14	08-07- 2016	Itraconazole	Photosensitivity reaction	For Drug Safety Label Change

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



सत्यमेव जयते



INDIAN PHARMACOPOEIA COMMISSION

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15	08-07- 2016	Ibuprofen	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	For Drug Safety Label Change
16	08-07- 2016	Amoxicillin/ Clavulanate Potassium	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	For harmonization of Drug Safety Label
17	08-07- 2016	Ciprofloxacin	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	For harmonization of Drug Safety Label
18	08-07- 2016	Sodium Valproate	Gum Hyperplasia	For harmonization of Drug Safety Label

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