



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	Febuxostat	For treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).	Allergic vasculitis
2	Oxcarbamazepine	Monotherapy or adjunctive therapy in the treatment of partial seizure, secondary generalized seizure, substitution for Carbamazepine can be made abruptly with an Oxcarbamazepine – to – Carbamazepine ratio of 300:200.	Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH).
3	Artemether & Lumefantrine	For treatment of uncomplicated falciparum malaria, mixed infections of falciparum and Chloroquine resistant vivax malaria.	Stevens- Johnson syndrome/Toxic epidermal necrolysis
4	Cefixime	Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by Enterobacteriaceae, H.influenza species.	Acute generalised exanthematous pustulosis (AGEP)

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