

File No. P.17019/01/2024-DA

Dated: March 27, 2024

Monthly Drug Safety Alert

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following;

Table

S. No.	Suspected Drugs	Indications	Adverse Drug Reactions
1	Cefuroxime	Antibiotic- Indicated for lower & upper respiratory tract infection, Urinary Tract Infection (UTI), gynaecological infection, skin or soft tissue infection etc.	Acute Generalized Exanthematous Pustulosis (AGEP)
2	Dutasteride + Tamsulosin	In the treatment of Benign Prostatic Hyperplasia	Palpitation
3	Nimesulide	<ul style="list-style-type: none"> Use in Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever. Acute pain in Orthopaedic, ENT, Dental and Post Operative condition. Additional indication; for short treatment of adult patients with inflammation & pain associated with arthritis, soft tissue, ENT condition, trauma, dental pain, Musculo skeletal & gynaecology & obstetric painful condition. For the treatment of pyrexia and inflammatory conditions in livestock 	Fixed Drug Eruption (FDE)
4	Beta blockers (Metoprolol, Propranolol, Atenolol)	Metoprolol: For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias,	Erectile dysfunction (Reversible)

		<p>prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.</p> <p>Propranolol: Cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine.</p> <p>Atenolol: For the treatment of hypertension, angina pectoris, cardiac arrhythmias</p>	
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Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling 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” and PvPI Helpline No. **1800-180-3024**.