# भारतीय भेषजसंहिता आयोग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार सैक्टर - 23, राज नगर गाजियाबाद - 201 002 (3.प्र.), भारत



INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar Ghaziabad - 201 002 (U.P.) INDIA

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## **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> <li>Use in Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever.</li> <li>Acute pain in Orthopaedic, ENT, Dental and Post Operative condition.</li> <li>Additional indication; for short treatment of adult patients with inflammation &amp; pain associated with arthritis, soft tissue, ENT condition, trauma, dental pain, Musculo skeletal &amp; gynaecology &amp; obstetric painful condition.</li> <li>For the treatment of pyrexia and inflammatory conditions in livestock</li> </ul>	Fixed Drug Eruption (FDE)
4	Beta blockers (Metoprolol, Propranolol, Atenolol)	<b>Metoprolol:</b> For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias,	Erectile dysfunction (Reversible)

INDIAN PHARMACOPOEIA (IP)

Official Book of Drug Standards in India

IP REFERENCE SUBSTANCES (IPRS)

Official Physical Standards for Assessing the Quality of Drugs NATIONAL FORMULARY OF INDIA (NFI)

Reference Book to Promote Rational Use of Generic Medicines

PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI)



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prevention of cardiac death and	
reinfarction after the acute phase of	
myocardial infarction, stable	
symptomatic CHF.	
<b>Propranolol:</b> Cardiac arrhythmias;	
tachycardia; hypertrophic obstructive	
cardiac myopathy; pheochromocytoma;	
thrombosis; management of angina;	
essential and renal hypertension;	
prophylaxis of migraine.	
<b>Atenolol:</b> For the treatment of	
hypertension, angina pectoris, cardiac	
arrhythmias	

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.

PHARMACOVIGILANCE PROGRAMME OF INDIA

Use of Generic Medicines