

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

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File No. IPC/NCC-PvPI/DSA/2017-18/05

May 2017

Drug Safety Alerts

The preliminary analysis of ADRs from the PvPI database reveals that the following drugs are associated with the risks as given below.

Table

Sl. No	Suspected Drugs	Indication	Adverse Reactions
1	Tinidazole	Amoebiasis, trichomoniasis and giardiasis, anaerobic infections, necrotising ulcerative gingivitis, bacterial vaginosis, H. Pylori associated peptic ulcers, abdominal surgery prophylaxis	Hyperpigmentation
2	Amlodipine	Angina, Hypertension, Coronary artery disease	Psoriasis
3	Hydroxyzine	For management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated	Bullous Pemphigoid
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4	Amitriptyline	Moderate to severe depression, migraine prophylaxis; tension type headache, neuropathic/chronic pain, fibromyalgia	Gingival Discolouration

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs. If such events are encountered please 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.