INDIAN PHARMACOPOEIA COMMISSION



National Coordination Centre- Pharmacovigilance Programme of India (PvPI) MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

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File No. IPC/NCC-PvPI/DSA/2016-17/

April 2016

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 Drugs | Indication | Adverse Reactions |
|------|-----------------|-------------------------------------------------------------------------------|-------------------|
| 1 | Roflumilast | Reduce the risk of Chronic Obstructive Pulmonary Diseases exacerbations | Gynecomastia |
| 2 | Clozapine | Management of Schizophrenic patients | Neutropenia |
| 3 | Disulfiram | Alcohol-Abuse Deterrent | Erythroderma |

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse events 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.