



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.

Tel No: 0120- 2783392, 2783400, 2783401, Fax: 0120-2783311

e-mail: pvpi@ipcindia.net, pvpi.ipc@gov.in, Web: www.ipc.gov.in

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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 | Ranibizumab | Neovascular Age-Related Macular Degeneration (AMD), Visual impairment due to Diabetic Macular Edema (DME), visual impairment due to Choroidal Neovascularization (CNV) secondary to Pathologic Myopia (PM). | Myocardial Infarction |
| 2 | Amphotericin B | Life threatening fungal infections including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis, blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis and candidiasis; visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds; severe meningitis. perioral candidiasis. | Bone Marrow Depression |
| 3 | Doxorubicin | Soft tissue and bone sarcomas, acute leukemia, malignant lymphoma, Hodgkin's diseases, breast carcinoma, small cell carcinoma of lungs, AIDS-related Kaposi's sarcoma, multiple myeloma. Gastrointestinal tract carcinoma, bladder cancer, ovarian carcinoma, acute myeloblastic leukemia, thyroid carcinoma, neuroblastoma. | Photosensitivity Reaction |
| 4 | Crizotinib | Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) – positive. | Pneumonitis, Hepatic Encephalopathy |

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