



P.17019/01/2019-PvPI
Indian Pharmacopoeia Commission
National Coordination Centre-Pharmacovigilance Programme of India
(Ministry of Health & Family Welfare, Govt. of India)

Sector-23, Rajnagar,
Ghaziabad-201002, U.P
Dated: March 25, 2019

Monthly Drugs Safety Alert

The preliminary analysis of Adverse Drugs Reactions from the PvPI database reveals that the following drug is associated with the risk as given below.

Table

Sl. No	Suspected Drugs	Indication	Adverse Drugs Reactions
1	Dabigatran	For prevention of stroke, systemic embolism and reduction of vascular mortality in adult patients with atrial fibrillation.	Alopecia
2	Sertraline	Major depressive disorders, Obsessive Compulsion Disorders (OCD), panic disorders.	Maculopathy

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above drugs. If such reactions 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**.