



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.ipc@gov.in, ipclab@vsnl.net, Web: www.ipc.gov.in

File No. IPC/NCC-PvPI/DSA/2018-19/05

11th September 2018

Drug Safety Alerts

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 Drug	Indication	Adverse Reaction
1	Fluoxetine	Bipolar disorder; Depressive Episode	Hypoacusis (Hearing Impairment)

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above drug. If such reaction is 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**.

“Let us join hands with PvPI to ensure patients safety”

ADR Reporting Help line (Toll Free): 1800-180-3024