

Drug Safety Alerts issued by Indian Pharmacopoeia Commission, National Coordination Center- Pharmacovigilance Programme of India from July – December 2021

Following are the alerts sent during the month of July to December 2021 by National Coordination Center, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad.

Healthcare Professional, Patients / Consumers are advised to closely monitor these ADRs associated with the use of suspected drugs.

S. No.	Month	Suspected Drug	Indication	Adverse Drug Reaction
1.	July 2021	Etoricoxib	For the treatment of pain, swelling & inflammatory conditions due to arthritis.	Acute Generalized Exanthematous Pustulosis (AGEP)
2.		Torsemide	For the treatment of oedema associated with congestive heart failure & hypertension.	DRESS Syndrome
3.		Quetiapine & Valproic Acid Interaction	Quetiapine: For the management of the manifestation of psychotic disorders (schizophrenia). For the additional indication "acute manic episode associated with bipolar disorder". Valproic Acid: As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure. As monotherapy or adjunctive therapy in the treatment of patients with complex partial seizure and manic episodes associated with bipolar disorder.	Neuropsychiatric Adverse Events (Depressed level of consciousness/Coma & Disorientation)
4.	August 2021	Sofosbuvir	In combination with other medicinal products for the treatment of chronic hepatitis C in adults.	Stevens-Johnson Syndrome
5.	September 2021	Dimethyl Fumarate	For Relapsing remitting multiple sclerosis	Alopecia
6.		Cefazolin	Cephalosporin antibiotic-indicated in the treatment of serious infections due to susceptible organisms – respiratory tract infections, urinary tract infections, skin & skin structure infection, biliary tract infections, septicaemia	Acute Generalized Exanthematous Pustulosis
7.	November 2021	Diclofenac	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery, migraine attack and postoperative inflammation in patients who have undergone cataract operation.	Skin hyperpigmentation
8.	December 2021	Remdesivir	Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19.	Sinus Bradycardia

Access this article online

Website: www.journalofsopi.com	For Reprints Contact at editorjournalofsopi@gmail.com
DOI: 10.21276/jpds.2020.18.02.03	

If such a reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form version 1.4 for HCPs or the Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>).

You can also use the Android Mobile App “ADR PvPI App” or the PvPI Helpline No. 1800-180-3024 (Toll Free), or report through a nearby Adverse Drug Reaction Monitoring Center (AMC).

Compiled by **Deepa Chaudhary (Pharmacovigilance Associate)** under the supervision of **Dr. Ratinder Jhaj (Coordinator)** and **Dr Balakrishnan S (Deputy Coordinator)**, Regional Training Centre cum ADR Monitoring Centre (RTC-AMC) Department of Pharmacology, All India Institute of Medical Sciences, Bhopal Madhya Pradesh (India).

