DEPARTMENT OF PHARMACOLOGY
ARMED FORCES MEDICAL COLLEGE, PUNE-40

Drug Safety Bulletin: Be Aware

Issue: Sixth; Oct-Dec 2022

Dear Readers,
The purpose of this bulletin is to disseminate important safety information related to drugs and medical devices from drug regulatory agencies like CDSCO, US FDA, European Union. This will help clinician to be aware of latest safety issues with drugs. The current issue highlights recent safety updates on codeine/ibuprofen, denisumab, vitamin B6 and alerts from PvPI database. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Increased risk of hypokalemia and Renal Tubular Acidosis with Codeine/Ibuprofen[1]

Having considered the available evidence, the Pharmacovigilance Risk Assessment Committee recommended to update Summary of Product Characteristics of codeine/ibuprofen with addition of following text in Special Warning and Precaution section "Severe hypokalaemia and renal tubular acidosis have been reported due to prolonged use of ibuprofen at higher than recommended doses. This risk is increased with the use of codeine/ibuprofen as patients may become dependent on the codeine component. Presenting signs and symptoms included reduced level of consciousness and generalised weakness. Ibuprofen induced renal tubular acidosis should be considered in patients with unexplained hypokalaemia and metabolic acidosis."

Risk of severe hypocalcemia with serious outcomes in patients with advanced kidney disease on dialysis treated with Denosumab[2]

Interim results from an ongoing safety study conducted by US-FDA suggests an increased risk of hypocalcemia, in patients with advanced kidney disease. These patients show a substantial risk with serious outcomes, including hospitalization and death. Health care professionals should consider the risks of hypocalcemia with the use of denosumab in patients on dialysis. When denosumab is used in these patients, adequate calcium and vitamin D supplementation and frequent blood calcium monitoring, possibly more often than is already being conducted, may help decrease the likelihood or severity of these risks. Advise patients on dialysis to immediately seek help if they experience symptoms of hypocalcemia.

Labelling Update regarding risk of Peripheral Neuropathy with Vitamin B6[3]

Therapeutic Goods Administration (TGA) of Australia added label warning for patients on risk of peripheral neuropathy with vitamin B6. This includes "Stop taking vitamin B6 if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible." The TGA has updated regulations for medicines containing Vit B6 as follows: 1. Products containing a daily dose of vitamin B6 above 10 mg require a warning about peripheral neuropathy. 2. The maximum permitted daily dose of vitamin B6 in individual products has been reduced from 200 mg to 100 mg for adults, with lower daily dose limits for children, depending on their age.

Important Drug Safety Alerts by PvPI Database[4]

Suspected Drug	Indication	ADRs
Terlipressin	Bleeding oesophageal varices	Atrial Fibrillation
Fluconazole	Candidiasis	Symmetrical Drug related intertriginous and Flexural Exanthema (SDRIFE)
Piperacillin + Tazobactam	LRTI/UTI/Intra-abdominal infection	Blurred vision

Source

1. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 28 Nov 2022 (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals)
2. US Food and Drug Administration. Drug Safety Communications. Last accessed on 28 Nov 2022 (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications)
3. Therapeutic Goods Administration (TGA) Australia. Last accessed on 28 Nov 2022 (https://www.tga.gov.au/)
4. Pharmacovigilance Programme of India (PvPI) Updates. Last accessed on 28 Nov 2022 (https://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/416-drug-safety-alerts.html)

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Department of Pharmacology
Armed Forces Medical College, Pune

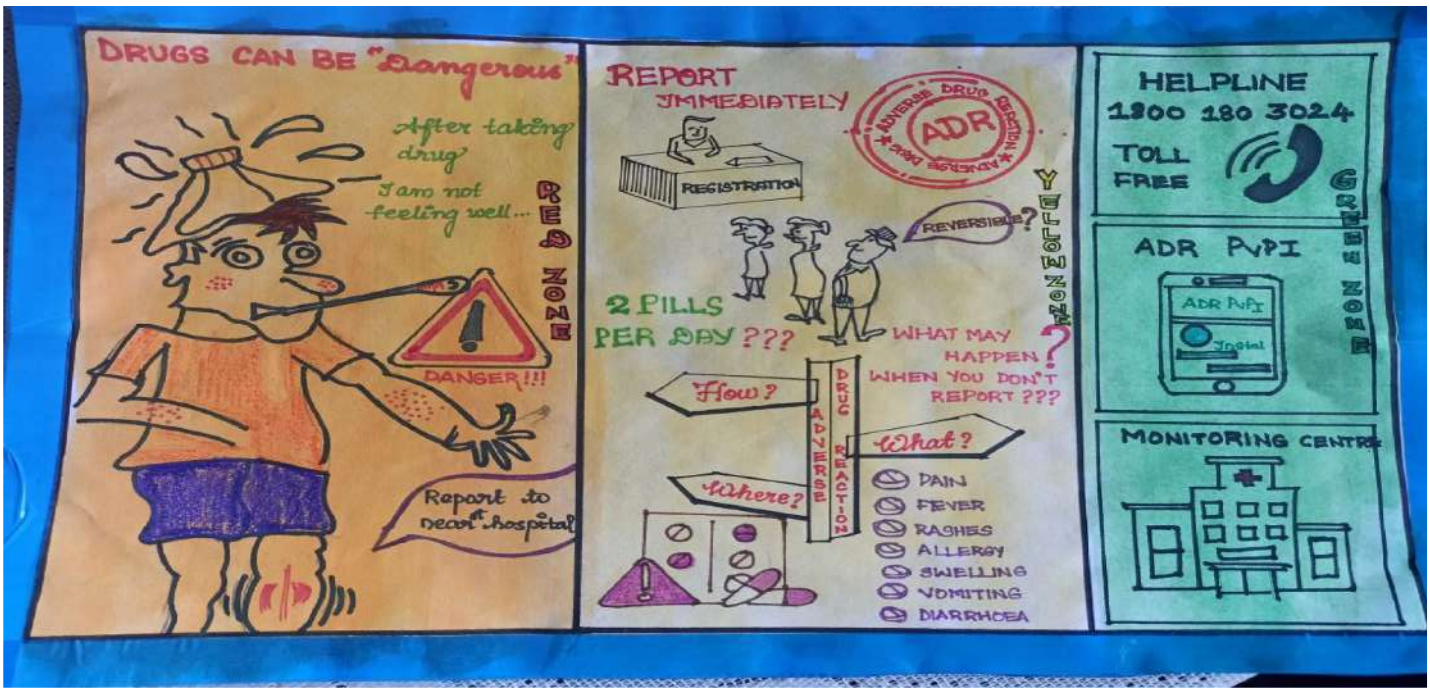
Adverse Drug Reaction Monitoring Centre(AMC)
under the aegis of Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission, Ghaziabad

National Pharmacovigilance Week (17 to 23 Sep 22)

Theme: Encouraging Reporting of ADRs by Patients

SENSITIZATION PROGRAMME AND HANDS ON EXERCISE ON ADR REPORTING FOR PHYSICIANS	SENSITIZATION OF PATIENTS TOWARDS MEDICATION SAFETY: INTERACTION WITH PATIENTS IN OPD/Wards	POSTER COMPETITION: THEME: ENCOURAGING REPORTING OF ADRs BY PATIENTS

Winner of E-Poster Competition



You are requested to report any observed ADRs to Dept of Pharmacology, ADR monitoring centre with following mode of communication:

1. **ADR form (Version 1.4) can be downloaded from IPC website. Link: https://www.ipc.gov.in/PvPI/adr.html**
2. **Contact Number: 9373239642**
3. **Email-ID: pvpiafmc@gmail.com**
4. **Google Form Link: https://docs.google.com/forms/d/e/1FAIpQLSfFWfSHemNQ56a3Pz5rfKe-jfZ2oumA0Xs_3kO4iYcs0-mr5Q/formResponse**
5.

Any Person **ADR** Any Time
Any Drug