DEPARTMENT OF PHARMACOLOGY
ARMED FORCES MEDICAL COLLEGE, PUNE-40

Drug Safety Bulletin: Be Aware

Issue: Eighth; Apr-Jun 2023

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 clinicians to be aware of latest safety issues with drugs. The current issue highlights recent safety updates on Levatinib, Progesterone, prescription stimulants, SGLT-2 inhibitors and alerts from PvPI database. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Lenvatinib – Adrenal insufficiency[1]

Having considered all available evidence, including non-clinical data (sinusoidal dilatation and cortical necrosis in the adrenal glands of rats and dogs at clinically relevant exposures), data from literature (including a case of positive de- and re-challenge) and a possible mechanism (inhibition of VEGF), Pharmacovigilance Risk Assessment Committee (PRAC) has agreed that a causal association between lenvatinib and adrenal insufficiency is considered as an at least reasonable possibility. Undesirable Effects section of Summary of product characteristics of Levatinib is updated with addition of following text "Lenvatinib monotherapy: frequency "uncommon": adrenal insufficiency; Combination with pembrolizumab: frequency "common": adrenal insufficiency"

Progesterone – Meningioma[1]

The PRAC of European Union has detected risk of meningioma with medicine containing progesterone. They have further advised to monitor this signal in periodic safety update report (PSUR) and further action will be taken based on reports of subsequent PSUR.

Warnings to improve safe use of prescription stimulants used to treat ADHD & other conditions[2]

To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the U.S. FDA has updated the Boxed Warning to ensure the prescribing information is made consistent across the entire class of prescription stimulants like amphetamine/dextroamphetamine, methylphenidate, dextroamphetamine, and methylphenidate. The updated text includes "ABUSE, MISUSE, AND ADDICTION: DRUG-X has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection. Before prescribing DRUG-X, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout DRUG-X treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction."

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Sensitization on SGLT-2 Inhibitors Related Genital Infections By NCC-PVPI

The National Coordination Center (NCC) for PvPI sensitized ADR monitoring Centres for monitoring and reporting of Adverse Reactions related to use of Sodium-Glucose Contransporter-2 (SGLT-2) inhibitors. The Healthcare Professionals are urged to report the Genital infection, Fournier's Gangrene, acute & chronic pancreatitis and other adverse events with use of SGLT-2 Inhibitors.

Apprise on VigiBase Data

VigiBase is the unique WHO global database of reported potential side effects of medicinal products. It is the largest database of its kind in the world, with over 30 million reports of suspected adverse effects of medicines, submitted, since 1968, by member countries of the WHO Programme for International Drug Monitoring (WHO PIDM). It is continuously updated with incoming reports. The purpose is to ensure that early signs of previously unknown medicines-related safety problems are identified as rapidly as possible.

Important Drug Safety Alerts by PvPI Database[3]

Suspected Drug	Indications	ADRs
Teneligliptin	Type 2 Diabetes Mellitus	Bullous Pemphigoid
Ceftriaxone	Treatment of infection caused by Pseudomonas species	ECG QT Prolongation
Levosulpiride	Depression and Schizophrenia	Restless Legs Syndrome

Source

1. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 08 Jul 2023 (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 08 Ju; 2023 (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications)
3. Pharmacovigilance Programme of India (PvPI) Updates. Last accessed on 08 Jul 2023(https://www.ipc.gov.in/PvPI/das.html)

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 / 9923693597**
3. **Email-ID: pvpiafmc@gmail.com**
4. **Google Form Link: https://docs.google.com/forms/d/e/1FAIpQLSew-Jyf5Sfruv1QyFggGksGQUGat34c-h7DajgCmhI8lVyTrg/viewform?usp=sf_link**

Any Person ADR Any Time Any Drug