

Drug Safety Bulletin: Be Aware

Issue: Seventh; Jan-Mar 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 Voriconazole/Flucloxacillin, Colistimethate Sodium, Bosutinib, Denosumab and alerts from PvPI database. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Voriconazole-Flucloxacillin Drug Interaction¹

The Pharmacovigilance Risk Assessment Committee (PRAC) has issued warning on drug interaction of voriconazole with flucloxacillin leading to subtherapeutic voriconazole levels. Sources from literature states that caution is needed when these two drugs are administered simultaneously. Flucloxacillin administration should be considered as contraindicated in patients being treated with voriconazole for invasive fungal infections. When the combination cannot be avoided, we recommend adding a second antifungal agent.

Colistimethate sodium for intravenous use – Pseudo-Bartter syndrome¹

The PRAC has identified the risk of Pseudo-Bartter syndrome with the use of IV Colistimethate sodium. The Warning and Precaution section of Summary of product characteristics (SPC) is updated with following text. “Few cases of pseudo-Bartter syndrome have been reported in children and adults with the intravenous use of colistimethate sodium. Monitoring of serum electrolytes should be started in suspected cases and appropriate management should be implemented, however, normalisation of electrolyte imbalance might not be achieved without discontinuation of colistimethate sodium.”

Bosutinib – Interstitial lung disease¹

The PRAC has identified the risk of Interstitial lung disease with use of bosutinib. The Undesirable Effects section of SPC is updated with following text. Undesirable Effects: “Frequency ‘not known’: Interstitial lung disease (ILD).” The Package Label mentions that signs of ILD include cough, difficulty breathing, painful breathing.

Denosumab - Risk of Severe Hypocalcemia in Patients on Dialysis²

The USFDA has identified the risk of severe hypocalcemia with serious outcomes, including hospitalization and death in patients with advanced kidney disease on dialysis treated with denosumab. 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.

Upcoming Training on Pharmacovigilance Skill Development by Indian Pharmacopoeia Commission (IPC)

Name of Programme: 25th Skill Development Programme on Pharmacovigilance of Medical Products

Date: 15 – 19 May 2023 (Through Webinar)

Registration Link:

https://docs.google.com/forms/d/e/1FAIpQLSdSvOUwLZcq2KO9xl-6gkJYpvARugJa53IWjf5G6GVF4y_QQ/viewform

Important Drug Safety Alerts by PvPI Database³

Suspected Drug	Indications	ADRs
Minoxidil	Alopecia (topical use)	Folliculitis
Amiodarone	Control of ventricular and supraventricular tachycardia	Acute Pancreatitis

Source

1. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 23 Mar 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 23 Mar 2023 (<https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications>)
3. Pharmacovigilance Programme of India (PvPI) Updates. Last accessed on 23 Mar 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-Jyf5Sfruv1QvFggGksGOUgat34c-h7DajgCmhI8IVyTrg/viewform?usp=sf_link

Any Person  Any Time
Any Drug

