

Drug Safety Bulletin: Be Aware

Issue: Fifth; Jul-Sep 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 clinicians to be aware of latest safety issues with drugs. The current issue highlights recent safety updates on clozapine, alemtuzumab, nomegestrol/chlormadinone, iodine containing contrast media and alerts from PvPI database. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Clozapine – Gastrointestinal hypomotility (reinforcement warning)¹

The Product Information of clozapine by Therapeutic Goods Administration (TGA) Australia has been updated to reinforce and expand on existing warnings that severe gastrointestinal adverse reactions have occurred with use of clozapine. Gastrointestinal hypomotility induced by clozapine may lead to hospitalisation, surgery and death. The warnings emphasise screening patients for constipation before starting and during treatment with clozapine, followed by treatment according to current clinical guidelines if necessary.

Alemtuzumab – Vitiligo²

The Pharmacovigilance Risk Assessment Committee (PRAC) has considered data from EudraVigilance, scientific literature, clinical data and additional data regarding the risk of vitiligo with alemtuzumab. The summary of product characteristics of alemtuzumab will be updated with addition of Vitiligo as adverse effect with frequency as ‘Uncommon’ in ‘Undesirable effects’ section.

Nomegestrol or chlormadinone - Meningioma²

The PRAC has identified the risk of meningioma with medicines containing nomegestrol or chlormadinone used for hormone replacement therapy/contraceptive. The PRAC has recommended that high-dose chlormadinone (5-10 mg) or high-dose nomegestrol (3.75–5 mg) should be used at the lowest effective dose and for the shortest duration possible, and only when other interventions are not appropriate. In addition, low- and high-dose nomegestrol or chlormadinone medicines must not be used by patients who have, or have had, meningioma.



Thyroid Monitoring in Young Children Receiving Iodine-Containing Contrast Media³

The US-FDA approved a new warning to the prescribing information for the entire class of iodinated contrast media (ICM) injections and monitoring recommendations for children 3 years or younger. The warning describes the risk of underactive thyroid or a temporary decrease in thyroid hormone levels. The conditions should be identified and treated early when needed to prevent potential future complications. These risks and recommendations pertain to ICM given as an injection through an artery or vein.

Important Drug Safety Alerts by PvPI Database⁴

Suspected Drug	Indications	ADRs
Fluconazole	Antifungal agent	Symmetrical Drug-related intertriginous Flexural Exanthema (SDERIFE)
Olzapine	Schizophrenia	Hyponatremia
Terlipressin	Bleeding Oesophageal Varices	Atrial Fibrillation

Source

1. Therapeutic Goods Administration (TGA) Australia. Last accessed on 11 Aug 2022 (<https://www.tga.gov.au/>)
2. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 11 Aug 2022 (<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals>)
3. US FDA Drug Safety, Last accessed on 11 Aug 2022 (<https://www.fda.gov/drugs/drug-safety-and-availability>)
24. Pharmacovigilance Programme of India (PvPI) Updates. Last accessed on 11 Aug 2022 (<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: 7385666876 / 9923693597
3. Email-ID: pvpi@fmc@gmail.com
4. Google Form Link: https://docs.google.com/forms/d/e/1FAIpQLSfFWfSHemNQ56a3Pz5rfKejfZ2oumA0Xs_3kO4iYcs0-mr5Q/viewform

Any Person  Any Time
Any Drug



