DEPARTMENT OF PHARMACOLOGY
ARMED FORCES MEDICAL COLLEGE, PUNE-40

Drug Safety Bulletin: Be Aware

Issue: First, Jul-Sep 2021

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 aware regarding latest safety issues with drugs. The current issue highlights recent safety updates on Hand sanitizer, Lamotrigene, NSAID, Canagliflozin, Alemtuzumab and Clindamycin. Feedback and suggestions, if any, may be sent at email Id: pvpiafmc@gmail.com.

Hand Sanitizer[1]

US FDA is warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based Hand Sanitizers to the skin and breathing in the vapors that linger.

FDA Advise: Use hand sanitizer in a well-ventilated area. Store hand sanitizer away from heat and flames. When using hand sanitizer, rub your hands until they feel completely dry and allow the vapors to clear before performing activities that may involve heat, sparks, static electricity, or open flames.

Lamotrigene[1]

US FDA advises that physicians should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Laboratory testing performed at therapeutically relevant concentrations has shown that lamotrigine can increase the risk of serious arrhythmias, which can be life-threatening, in patients with clinically important structural or functional heart disorders. Clinically important structural and functional heart disorders include heart failure, valvular heart disease, congenital heart disease, conduction system disease, cardiac channelopathies such as Brugada syndrome, ischemic heart disease, or multiple risk factors for coronary artery disease. The risk of arrhythmias may increase further if used in combination with other medicines that block sodium channels in the heart. Other sodium channel blockers approved for epilepsy, bipolar disorder, and other indications should not be considered safer alternatives to lamotrigine in the absence of additional information.

Avoiding use of NSAIDs in pregnancy at 20 weeks or later[1]

US FDA is warning that use of NSAIDs around 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation. Complications of prolonged oligohydramnios may include limb contractures and delayed lung maturation. In some post-marketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.

FDA Advise: If NSAID treatment is deemed necessary between 20 to 30 weeks of pregnancy, limit use to the lowest effective dose and shortest duration possible. As currently described in the NSAID labels, avoid prescribing NSAIDs at 30 weeks and later in pregnancy because of the additional risk of premature closure of the fetal ductus arteriosus. The above recommendations do not apply to low-dose 81 mg aspirin prescribed for certain conditions in pregnancy. Consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours. Discontinue the NSAID if oligohydramnios occurs and follow-up according to clinical practice.

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US FDA removes boxed warning about risk of leg & foot amputations for canagliflozin[1]

US FDA removed boxed warning about risk of leg and foot amputations from canagliflozin label based on safety information from recent clinical trials which suggested that the risk of amputation, while still increased with canagliflozin, is lower than previously described, particularly when appropriately monitored. The amputation risk with canagliflozin remains and is still described in the warnings and precautions section of the prescribing information.

Alemtuzumab - Sarcoidosis[2]

Pharmacovigilance Risk Assessment Committee (PRAC) of European Medicines Agency has considered available evidence pertaining to risk of sarcoidosis with alemtuzumab, ascertained from EudraVigilance, the literature and clinical data. The PRAC recommended to update summary of product characteristics (SPC) of Alemtuzuma with following text. "There have been reports of an immune system disorder (sarcoidosis) in patients treated with alemtuzumab. Symptoms can include persistent dry cough, shortness of breath, chest pain, fever, lymph node swelling, weight loss, skin rashes, and blurred vision." *Frequency:* Uncommon – may affect up to 1 in 100 people

Clindamycin - Acute Kidney injury[2]

Having considered the available evidence in EudraVigilance, the literature, and clinical data, the PRAC recommended to update SPC of clindamycin with addition of following text. "Acute kidney injury, including acute renal failure, has been reported with clindamycin formulations infrequently. Therefore, monitoring of renal function should be considered in patients receiving prolonged therapy, suffering from pre-existing renal dysfunction or taking concomitant nephrotoxic drugs." *Frequency:* Unknown

Source

1. US Food and Drug Administration. Drug Safety Communications. Last accessed on 16 Jul 2021 (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications)
2. Pharmacovigilance Risk Assessment Committee (PRAC). European Medicines Agency. Last accessed on 16 Jul 2021 (https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-3-6-may-2021-prac-meeting_en.pdf)

We run Adverse Drug Monitoring Center at Dept of Pharmacology, since year 2014. We collect data related to observed ADRs by Active as well as Passive Surveillance, analyze the data, enter in to a software named VIGIFLOW and forward the report to Indian Pharmacopoeia Commission, Ghaziabad (National Coordination Center-WHO UMC Collaborating Center) for necessary action.
You are requested to report any observed Adverse Drug Reactions to following mode of communication:

1. Contact Number: 7385666876
2. Email-ID: pvpiafmc@gmail.com
3. Google Form Link: https://docs.google.com/forms/d/e/1FAIpQLSfFWfSHemNQ56a3Pz5rfKe-

If you SEE something, SAY something!!...If you SAY something, DO something!!...