Serious Risks/Safety Information – USFDA

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) – USFDA

The USFDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

The appearance of a drug on this list does not mean that conclusive of the risk. It means that FDA has identified ***potential safety issue*** but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines whether the drug is associated with the risk or not and it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS) or gathering additional data to better characterize the risk.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information
October - December 2019				
Antimigraine	Erenumab	Subcutaneous	Hypertension	Evaluation is in progress.
Central Nervous System Agent	Suvorexant	Oral	Fall, serious injuries	The labeling section of the product was updated to include falls.
Antiviral	Sofosbuvir and Velpatasvir; Ledipasvir and Sofosbuvir; Sofosbuvir, Velpatasvir, and Voxilaprevir	Oral	Interaction with bariatric surgery: treatment failure	Evaluation is in progress.
Antidiabetic/ Glucagon-like peptide-1 (GLP-1) receptor agonists	Lixisenatide, exenatide, semaglutide, liraglutide, insulin glargine and lixisenatide, albiglutide, dulaglutide, insulin degludec and liraglutide	Subcutaneous	Diabetic Ketoacidosis	Evaluation is in progress.
Anti-Infective Agent	Miltefosine	Oral	Eye disorders	Evaluation is in progress.
Immune Modulator	Ocrelizumab	Intravenous	Serious herpes viral infection	Evaluation is in progress.
Proton pump inhibitors	Rabeprazole, dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole	Oral	Acute generalized exanthematous pustulosis (AGEP)	Evaluation is in progress.
Central Nervous System Agent	Riluzole	Oral	Pancreatitis	Evaluation is in progress.
Endocrine-Metabolic Agent	Vasopressin	Intravenous	Diabetes insipidus	The labeling section of the product was updated to include the risk of diabetes insipidus.

References:

1. http://www.fda.gov/
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2020, IBM Corporation 2020.

❑