SFDA

Safety Communication

[12/03/2024]

Potential Risks of Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS) Associated with Use of Pseudoephedrine-Containing Medicines

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about the potential risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) with the use of pseudoephedrine-containing medicines.

PRES is a rare condition characterized by cerebral edema, wherein specific parts of the brain undergo swelling. This phenomenon commonly arises from underlying etiological factors, such as markedly elevated blood pressure, kidney dysfunction, severe infections, certain medications, select autoimmune disorders, and pre-eclampsia. Typically, the diagnostic process involves the utilization of brain imaging, which facilitate the identification and localization of swelling areas. While, RCVS is an uncommon disorder that arise from transient constriction in the blood vessels of the brain. The typical method of diagnosing RCVS involves conducting brain imaging with angiography to detect any constrictions in the cerebral blood vessels supplying the brain. Pseudoephedrine, either on its own or in combination with other substances, has been approved by SFDA as a symptomatic relief of nasal or sinus congestion caused by the common cold or allergic rhinitis.

Globally, there have been reported small number of PRES and RCVS cases with the use of pseudoephedrine-containing medicines. Nonetheless, the majority of these cases were resolved after discontinuing pseudoephedrine and no fatal cases due to PRES or RCVS have been reported.

Based on the available evidence, the SFDA has requested labeling update of all pseudoephedrine-containing medicines, as following:

There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately if signs or symptoms of PRES/RCVS develop.

Advice for healthcare professionals:

- Patients who have severe or uncontrolled hypertension, severe renal disease, should not use pseudoephedrine-containing medicines. This is because these medical conditions might increase the risk of experiencing PRES or RCVS.
- Symptoms of PRES include a diverse range of acute or subacute neurological manifestations, such as headache, changes in mental status, seizures, visual disturbances, and focal neurological deficits. These symptoms typically have a sudden or relatively gradual onset, occurring over a period of hours to days. Usually, PRES is often reversible, as the symptoms generally resolve within several days or weeks when blood pressure is reduced and any medications causing the condition are discontinued.
- Symptoms of RCVS consist of an intense thunderclap headache, characterized by severe pain that reaches its peak within seconds. This type of headache usually affects both sides of the head and starts at the back, followed by widespread pain often accompanied by feelings of nausea, vomiting, sensitivity to light (photophobia), and sensitivity to sound (phonophobia). Certain patients may experience temporary focal deficits. The syndrome's primary complications are ischemic stroke and hemorrhagic stroke.
- Patients should be advised to immediately stop using these medicines and seek medical assistance if signs or symptoms of PRES or RCVS are developed.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

aRMM: