Direct Healthcare Professional Communication

May 2024

Pseudoephedrine – Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you **about Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)**

Summary:

- Few cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing medicines.

- Pseudoephedrine-containing medicines are contraindicated in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease or renal failure, as these conditions increase the risks of PRES or RCVS.

- Symptoms of PRES and RCVS include sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.

- Patients should be advised to immediately stop using these medicines and seek medical assistance if signs or symptoms of PRES or RCVS develop.

Background on the safety concern

Pseudoephedrine is authorised, alone or in combination with other substances, for short-term symptomatic relief of nasal or sinus congestion caused by the common cold or allergic rhinitis <or vasomotor rhinitis><or aerotitis>.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), which are serious conditions affecting the cerebral blood vessels, have been reported in patients taking pseudoephedrine-containing medicines. Most reported cases resolved following discontinuation and appropriate treatment. No fatal cases of PRES or RCVS have been reported.

Following an EU-wide review of reported cases and other available data to evaluate the risks of PRES and RCVS with pseudoephedrine-containing medicines, it has been concluded that pseudoephedrine is associated with risks of PRES and RCVS and that the product information

should be updated to include information on these adverse reactions and measures to reduce the risks.
The newly identified risks of PRES or RCVS should be considered in the context of the overall safety profile of pseudoephedrine, which also includes other cardiovascular and cerebrovascular ischaemic events.

Reference:

EMA:https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-pseudoephedrine-risks-posterior-reversible-encephalopathy-syndrome-pres-reversible-cerebral-vasoconstriction-syndrome-rcvs_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301