DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

OF THE ITALIAN MEDICINES AGENCY

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

Dear Healthcare professional,

The marketing authorisation holders of medicinal products containing pseudoephedrine, in agreement with the European Medicines Agency (EMA) and the Italian Medicines Agency (AIFA) would like to inform you of the following:

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.

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.

Overview of PRES and RCVS

PRES can manifest with a wide variety of acute or subacute neurological symptoms, including headache, mental status alteration, seizures, visual disturbances and/or focal neurologic deficits. An acute or sub-acute onset of the symptoms (hours to days) is typical. PRES is usually reversible; symptoms cease within several days or weeks with the reduction of blood pressure and withdrawal of causative drugs.

RCVS usually manifests with thunderclap headache (severe pain peaking in seconds), typically bilateral, with posterior onset followed by diffuse pain frequently accompanied by nausea, vomiting, photophobia and phonophobia. Transient focal deficits can be present in some patients. Ischaemic and haemorrhagic stroke are the major complications of the syndrome.

Call for reporting

Please report any suspected adverse reactions associated with the use of pseudoephedrine in accordance with the national requirements via the national spontaneous reporting system, to:

https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse

AIFA takes this opportunity to remind all healthcare workers of the importance of reporting suspected adverse drug reactions, as an indispensable tool for confirming a favorable benefit-risk ratio in real conditions of use.

Reports of Suspected Adverse Drug Reactions must be sent to the Pharmacovigilance Responsible of the structure to which the Operator belongs.