Risk of serious side effects with medicines containing pseudoephedrine

Safety alert

The Botswana Medicines Regulatory Authority (BoMRA) would like to inform you about a safety concern regarding medicines containing pseudoephedrine. Pseudoephedrine is used to relieve nasal, or sinus congestion caused by the common cold, sinusitis, and hay fever and other respiratory allergies. Recent evidence suggests a potential risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) associated with the use of these medicines containing pseudoephedrine.

Background of safety concern

Pseudoephedrine (PSE) and ephedrine (E) are alkaloids derived from various species of Ephedra spp. of the Ephedraceae family. Pseudoephedrine is a sympathomimetic with a mixed mechanism of action, direct and indirect. It indirectly stimulates alpha-adrenergic receptors, causing the release of endogenous norepinephrine (NE) while it directly stimulates beta-adrenergic receptors. This causes the blood vessels to constrict (narrow) hence reducing the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose.

In Botswana, several pseudoephedrine-containing medicines are registered, available either through prescription (Schedule 2) or over the counter (Schedule 3). It's important to note that all registered pseudoephedrine-containing medicines in Botswana are administered orally.

The Authority has reviewed all available evidence, including post-marketing safety data, which concluded that pseudoephedrine is associated with risks of PRES and RCVS. It's important to note that PRES and RCVS are rare conditions that can result in reduced blood supply to the brain, potentially leading to severe and life-threatening complications. However, with timely diagnosis and appropriate treatment, symptoms of PRES and RCVS typically resolve.

As of 26th February 2024, globally there were 16542 suspected adverse drug reactions (ADRs) reported associated with pseudoephedrine-containing medicines. Among these reported ADRs, there have been 11 cases of RCVS and 2 cases of PRES documented in the global database. However, it is important to note that there have been no suspected ADRs reported specifically for adverse drug reactions associated with pseudoephedrine-containing medicines in Botswana. However, it is essential to continue monitoring the safety of medicines to protect public health. BoMRA will request all marketing authorization holders selling pseudoephedrine-containing medicines to update patient information leaflets and product information as a new measure to be taken to minimize the risk.

Advice to healthcare professionals

Pseudoephedrine-containing medicines should not be used in patients with severe or uncontrolled hypertension or severe acute or chronic kidney disease or renal failure, as these conditions are considered risk factors for developing PRES or RCVS.

Patients should be educated about the symptoms of PRES and RCVS and advised to discontinue treatment and seek immediate medical assistance if the following symptoms occur;

- severe headache
- nausea
- vomiting
- confusion
- seizures and/or
- visual disturbances

Healthcare professionals should carefully consider the risks of PRES and RCVS alongside other potential risks associated with pseudoephedrine-containing medicines, including cardiovascular or ischemic events.

The decision to prescribe or recommend these medications should be made after weighing the benefits against the potential risks, especially in patients with pre-existing cardiovascular or renal conditions.

How to report adverse drug reactions

Report any suspected ADRs or any discomfort experienced by a patient to BoMRA using any of the following BoMRA platforms:

1. ADR reporting forms: You may download the forms from the BoMRA website **www.bomra.co.bw** and email the completed form to **reportadr@bomra.co.bw.**
2. E-reporting: Follow the Primary eReporting (who-umc.org) link available on BoMRA website and complete the form online. BoMRA Regulatory Information Management System (BRIMS) Portal (bomra.co.bw) **https://brims.bomra.co.bw/#/public/app-home.**
3. MedSafety App: Use the ADRs reporting App, available on Apple store or Google store for smart phones.
4. Phone reporting: Call BoMRA at **373 1727/20.**
5. Information and Support: For more information on medicine/vaccine safety, contact **BoMRA National Medicines Information Centre** at **373 1788/71** or via **nmic@bomra.co.bw.**

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Promoting access to safe medicines