

IMPORTANT SAFETY INFORMATION

07 April 2025

Pseudoephedrine-containing medicines– Risks of Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS)

Dear Healthcare Professional,

Reckitt Benckiser Pharmaceuticals (Pty) Ltd in collaboration with the South African Health Products Regulatory Authority (SAHPRA), wish to draw your attention to the risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome associated with the use of pseudoephedrine-containing medicines.

Summary

- 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.

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

Commercial Site:

Ground Floor, North Wing, Allandale Building, 39 Magwa Crescent, Waterfall, 2090

Manufacturing Site:

8 Jet Park Road, Elandsfontein, 1406

P.O. Box 164, Isando, 1600

T: +27 11 871 1611 W: [Reckitt.com](https://www.Reckitt.com)

(Reg. No. 1943/016101/07) Directors: I Ntostas; V.R Govind

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.

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 medicines.

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.

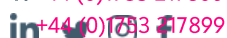
Cases of PRES and RCVS, which are serious conditions affecting the cerebral blood vessels, have been reported in patients taking pseudoephedrine-containing medicines. Most reported cases resolved following discontinuation and appropriate treatment. No fatal cases of PRES or RCVS have been reported.

Advice for healthcare professionals to provide to patients:

- Pseudoephedrine-containing medicines are for short-term use only, used to relieve symptoms of nasal and sinus congestion with colds, flu and allergies. Healthcare professionals are urged to remind patients to follow the instructions for use in the Patient Information Leaflet (PIL).
- Patients should be alerted about PRES and RCVS cases reported with the use of pseudoephedrine-containing medicines. Furthermore, patients should be informed that these conditions are rare and can involve inflammation and/or reduced blood supply to the brain.
- Patients should be advised to stop taking pseudoephedrine-containing medicines and seek urgent medical attention if they experience severe headache that develops very quickly or suddenly feel sick or are vomiting, confused or experiencing seizures or changes in vision.
- Healthcare professionals should warn patients not to take pseudoephedrine-containing medicines if they have very high blood pressure (hypertension), uncontrolled hypertension, severe acute (sudden) or chronic (long-term) kidney

Reckitt Group plc (Global Headquarters)
Turner House, 103-105 Bath Road, Slough,
Berkshire, SL1 3UH, UK

T: +44 (0)1753 217800 W: [Reckitt.com](https://www.Reckitt.com)

in  +44 (0)1753 217899

disease or kidney failure. Patients should be encouraged to seek advice from their doctor or pharmacist if they are unsure whether side effects experienced after taking these medicines are related to PRES or RCVS.

- Patients need to be enlightened that non-serious side effects, which are typically mild, may be experienced after using any medicine. Patients need to be aware of the importance of using PIL for guidance and seeking advice from a doctor or pharmacist if they experience side effects associated with the use of pseudoephedrine-containing medicines.

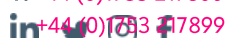
Advice to healthcare professionals:

- Please be reminded that pseudoephedrine-containing medicines are for short term use only and should not be used for prolonged or extended use.
- If signs and symptoms suggestive of PRES and RCVS, pseudoephedrine-containing medicines should be withdrawn immediately, and an alternative treatment considered (as appropriate).
- If a patient has developed PRES and RCVS with the use of pseudoephedrine-containing medicines, treatment with these medicines must not be restarted at any time.
- Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality problems associated with the use of the product indicated below to SAHPRA via the following eReporting link <https://primaryreporting.who-umc.org/ZA> available on the SAHPRA website (www.sahpra.org.za).
- Alternatively, healthcare professionals may complete an ADR reporting form accessible via this link <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reportingform/> and email it to adr@sahpra.org.za.
- Additionally, reporting can be done via the Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or App Store. For more information on Med Safety App, please use the following link: <https://medsafety.sahpra.org.za/>.
- For more information on ADR reporting of the associated product indicated below, please contact the SAHPRA Pharmacovigilance unit at pvqueries@sahpra.org.za or alternatively contact Reckitt Benckiser via email at SouthAfricaDSO@reckitt.com or call 0861 111 100.

The Professional Information (PI) and Patient Information Leaflet (PIL) of the associated product indicated below will be updated accordingly.

Reckitt Group plc (Global Headquarters)
Turner House, 103-105 Bath Road, Slough,
Berkshire, SL1 3UH, UK

T: +44 (0)1753 217800 W: Reckitt.com


 Social media icons for LinkedIn, YouTube, Instagram, and Facebook, followed by the phone number +44 (0)1753 217899.

Associated product:

Product name	Active ingredients	Registration number	Clinical indication
<i>Nurofen Cold and Flu (tablets)</i>	<i>Ibuprofen 200 mg and Pseudoephedrine hydrochloride 30 mg per tablet</i>	<i>Z/5.8/256</i>	<i>Relief of symptoms of colds and flu, including aches and pains, headaches, fever, sore throat, blocked nose and sinuses</i>

Reckitt Group plc (Global Headquarters)
 Turner House, 103-105 Bath Road, Slough,
 Berkshire, SL1 3UH, UK

T: +44 (0)1753 217800 **W:** Reckitt.com

in  +44 (0)1753 217899

Reckitt refers to entities in the Reckitt Group plc group of companies.





Salome m Sebata

Ms Salome Sebata

Responsible Pharmacist

Mobile: 082 789 8539

Fax: 086 583 6697

Email: salome.sebata@reckitt.com

**Reckitt Benckiser
Pharmaceuticals (Pty) Ltd**

Ground Floor, North Wing,
Allandale Building,
39 Magwa Crescent, Waterfall
2090
P.O. Box 164, Isando, 1600
T +27 11 871 1611