Product Information as approved by the CHMP on 25 January 2024, pending endorsement by the European Commission

Annex III

Amendments to relevant sections of the product information

Note:

These amendments to the relevant sections of the product information are the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

Amendments to relevant sections of the product information

[For all products in Annex I, the existing product information shall be amended (insertion, replacement or deletion of the text, as appropriate) to reflect the agreed wording as provided below]

A. Summary of Product Characteristics

4.3 Contraindications

[The following contraindications should be inserted]

- **Severe hypertension or uncontrolled hypertension**
- **Severe acute or chronic kidney disease/renal failure**

4.4 Special warnings and precautions for use

[A warning should be added as follows]

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

4.8 Undesirable effects

[The following adverse reactions should be added or revised under the SOC 'Nervous system disorders' with a frequency 'Not known']

Posterior reversible encephalopathy syndrome (PRES) (see section 4.4)

Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

B. Package Leaflet

Section 2. What do you need to know before you take <Product Name>

Do not take/use <Product Name>

- **if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication**
- **if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure**

Warnings and precautions

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using <Product Name> immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms)

Section 4. Possible side effects

*[The following most serious side effect needs to be listed **first** in section 4]*

Not known: frequency cannot be estimated from the available data

- **serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)**

Stop using <Product Name> immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- **severe headache with a sudden onset**
- **feeling sick**
- **vomiting**
- **confusion**
- **seizures changes in vision**