

SB TITCK 21.03.2024 PSÖDOEFEDRİN İÇEREN İLAÇLAR-ACIL GÜVENLİLİK KISITLAMASI_EN

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-1424975 21.03.2024 Subject: Pseudoephedrine-containing products / Urgent Safety Alert

FILE

It has been announced that the warnings recommended by the Pharmacovigilance Risk Assessment Committee (PRAC), and approved by the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency (EMA), regarding all pseudoephedrine-containing drugs (both for single and combination use) to mitigate the risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), will be included in the product information for all pseudoephedrine-containing drugs in Europe. The Agency has given consideration to the proposed warnings, and the statements described in the attachment must be incorporated in local summary of product characteristics (KÜP) and package leaflet (KT) of the products concerned, which are marketed in Türkiye. KÜBs for reference products incorporating the requisite changes must be submitted to the Pharmacologic Assessment Unit for review within 15 days of this announcement. Submissions for other products containing pseudoephedrine must be made to the Pharmacologic Assessment Unit within 15 days after the KÜB for the reference product has been posted on the Agency's official website. For products which contain this active substance but which has no reference, or an actively marketed reference, submissions must be made to the Pharmacologic Assessment Unit within 15 days after this announcement, without waiting for posting of KÜB on the Agency's official website for any reference product. For your information and appropriate action.

Dr. Asım Hocaoglu Agency President

Distribution: Turkish Pharmaceutical Manufacturers' Association Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers' Association of Türkiye Health Products Association

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[Product information of all products must be revised as follows (add, revise or delete text as appropriate)]

Local Summary of Product Characteristics (KÜB)

4.3 Contraindications [Incorporate the following contraindications]

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

4.4 Special warnings and precautions for use [Incorporate the following warning]

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 (headache that starts and reaches climax rapidly), 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 [Revise as appropriate or incorporate the following adverse reactions in System Organ Class, under the section "Nervous system disorders" with a frequency of

“Unknown”]

Posterior reversible encephalopathy syndrome (PRES) (see Section 4.4) Reversible cerebral vasoconstriction syndrome (RCVS) (see Section 4.4)

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Local Package Leaflet (KT)

2. What you need to know before you take <product name> [Incorporate the following]

DO NOT TAKE <product name> in the following cases:

- Very high blood pressure (severe hypertension) or hypertension not controlled by your medication - Severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

EXERCISE CAUTION when using <product name> in the following cases: 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).

4. Possible side effects [The most serious side effect below should 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 assistance if you develop the following symptoms which may be signs of posterior reversible encephalopathy syndrome (PRES) or reversible cerebral vasoconstriction syndrome (RCVS):

Severe headache with a sudden onset Feeling sick Vomiting Confusion Seizures, changes in vision

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