

Safety Alert

Aug 2024

Pseudoephedrine – risk of abuse to be added as a new warning

EDA performs label update to include the following:

Special warnings and precautions for use

Risks of abuse

Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded.

Background:

Therapeutic Indication

Therapeutic indications For the symptomatic relief of the symptoms of colds and influenza including feverishness, aches and pains, headache, nasal and sinus congestion (blocked nose and sinuses).

Contraindication:

- Severe renal impairment
- Cardiovascular disease including hypertension or uncontrolled hypertension and peripheral vascular disease.
- Severe acute or chronic kidney disease/ renal failure
- Diabetes mellitus
- Pheochromocytoma
- Hyperthyroidism
- Closed angle glaucoma or where intraocular pressure is raised
- Severe liver disease
- Concomitant use of other sympathomimetic decongestants:
 - Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment)
 - Beta-blockers
- Not to be used in children under the age of 6 years

Abuse

Is the intentional, non-therapeutic use of a drug, even once, for its desirable 217 psychological or physiological effects

References:

EMA ([Click here](#))