Health Canada Santé Canada

NATURAL HEALTH PRODUCT

PSEUDOEPHEDRINE
Adolescents 12-17 years and Adults

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Compliance with Precursor Control Regulations

The *Precursor Control Regulations* (PCR) (JC 2018) allows Canada to fulfill its international obligations with respect to the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988,* and provides a framework for the regulation of activities involving precursor chemicals which can be used in the production of illicit drugs and substances. Under the PCR, regulated chemicals are grouped into two classes: Class A and Class B. For Class A precursors such as pseudoephedrine and/or products containing them, persons wishing to be involved in activities such as importation, exportation, production, packaging, selling, and/or providing must first obtain a licence.

Further information regarding compliance with the PCR, including application forms and guidance documents pertaining to the application for a Class A precursor licence, is available at: http://www.healthcanada.gc.ca/precursors

Date September 25, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)
		Common name(s)
▸ (1S,2S)-2-Methylamino-1-phenylpropan-1-ol ▸ (alphaS)-alpha-[(1S)-1-(Methylamino)ethyl]benzenemethanol ▸ d-psi-Ephedrine	Pseudoephedrine	▸ Pseudoephedrine ▸ Pseudoephedrine hydrochloride ▸ Pseudoephedrine sulfate

References: Proper names: NLM 2018, O'Neil et al. 2018; Common name: NLM 2018, O'Neil et al. 2018; Source materials: NLM 2018, O'Neil et al. 2018.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- Used as a decongestant/to relieve nasal congestion (due to hay fever/allergic rhinitis /allergies/sinusitis/the common cold/flu) (O'Neil et al. 2018; HC 2009; Williamson 2003; Mills and Bone 2000; Simons et al. 1996; Bright et al. 1981; Bye et al. 1980; Empey et al. 1980).
- Nasal decongestant (O'Neil et al. 2018; HC 2009; Williamson 2003; Mills and Bone 2000; Bright et al. 1981; Bye et al. 1980).

Dose(s)

Subpopulation(s)

Adolescents 12 to 17 years and Adults 18 years and older

Quantity(ies)

60-240 milligrams of pseudoephedrine per day; Not to exceed 60 milligrams per single dose (Simons et al. 1996; Empey et al. 1980; Dickerson et al. 1978).

Direction(s) for use

Take a single dose every 4-6 hours up to 4 times a day (HC 2009).

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (Mills and Bone 2005; US FDA 2004; Blumenthal et al 2000).

Risk information

Caution(s) and warning(s)

- Keep out of reach of children (HC 2009).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen.
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are pregnant or breastfeeding (Brinker 2010; CRN 2000; Carruthers-Czyzewski 1996; Mortimer 1977).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are taking medication and/or natural health products for allergy symptoms, asthma, cough/cold or weight control (HC 2009; Mills and Bone 2005; Naik and Freudenberger 2004).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are taking other products which contain caffeine, ephedrine, phenylpropanolamine or pseudoephedrine (Brinker 2010; Mills and Bone 2005; Greenway et al. 2004; Naik and Freudenberger 2004).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have cardiovascular disease, diabetes, difficulty in urination due to prostate enlargement, glaucoma, thyroid problems, seizure disorders or a pre-existing psychiatric condition (Brinker 2010; HC 2009; Eccles 2006; Bensky et al. 2004; Williamson 2003; Blumenthal et al. 2000; Mills and Bone 2000; Carruthers-Czyzewski 1996).

Contraindication(s)

Do not use this product if you are taking, or have taken monoamine oxidase inhibitors in the past two weeks (Brinker 2010; Eccles 2006; Mills and Bone 2005; Blumenthal et al. 2000; Carruthers-Czyzewski 1996).

Known adverse reaction(s)

Stop use in case of restlessness, irritability, dizziness, tremor, severe headache, insomnia, loss of appetite, nausea, rapid heartbeat, shortness of breath and/or disturbance of urination (Mills and Bone 2005; Bensky et al. 2004; Blumenthal et al. 2000; Dickerson et al. 1978).

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage Conditions

Store protected from light and moisture (BP 2009; USP 32 2009; Ph. Eur. 2007).

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

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