Pseudoephedrine for Adolescents 12-17 years and Adults

PSEUDOEPHEDRINE Adolescents 12-17 years and Adults Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 82 KB) 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 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 on the label. This monograph cannot be combined with any other monograph at Class II. Theses products may be submitted as a Class III application along with evidence to support their safety and efficacy. Compliance with Precursor Control Regulations The Precursor Control Regulations (PCR) (JC 2024) 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 April 25, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source ingredient(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: NIH 2024; RSC 2024; Common name: NIH 2024; RSC 2024; Source information: NIH 2024; RSC 2024. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Used as a decongestant (for the common cold) (US FDA 2022; HC 2009; Williamson 2003; Mills and Bone 2000; Simons et al. 1996; Bright et al. 1981; Bye et al. 1980; Empey et al. 1980). Temporarily relieves/For the temporary relief of cold/(and) flu symptoms such as nasal congestion/sinus congestion/stuffy nose/nasal stuffiness (US FDA 2022; HC 2009; Williamson 2003; Mills and Bone 2000; Simons et al. 1996; Bright et al. 1981; Bye et al. 1980; Empey et al. 1980). Temporarily relieves/For the temporary relief of nasal congestion/sinus congestion/stuffy nose/nasal stuffiness (due to hay fever/allergic rhinitis/the common cold) (US FDA 2022; 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 (US FDA 2022; HC 2009; Williamson 2003; Mills and Bone 2000; Simons et al. 1996; Bright et al. 1981; Bye et al. 1980; Empey et al. 1980). Note: The above uses can be combined on the product label (e.g., Nasal decongestant to temporarily relieve nasal congestion due to the common cold). Dose(s) Subpopulation(s) Adolescents 12-17 years, Adults 18 years and older Quantity(ies) 60 - 240 milligrams of pseudoephedrine per day; Not to exceed 60 milligrams per single dose (US FDA 2022; 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 per day (US FDA 2022). Duration(s) of Use Ask 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. In case of overdose, call a poison control centre or get medical help right away (US FDA 2022; HC 2009). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last for more than 7 days (US FDA 2022). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms are accompanied by a high fever that lasts longer than 3 days, the production of thick yellow/green phlegm, rash or

a persistent headache. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; CRN 2000; Carruthers-Czyzewski 1996; Mortimer 1977). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking any other cough and cold or weight control medications or prescription drugs, or products which contain caffeine or ephedrine (Brinker 2010; HC 2009; Mills and Bone 2005; Greenway et al. 2004; Naik and Freudenberger 2004). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have asthma, diabetes, glaucoma, heart disease, high blood pressure, kidney disease, difficulty urinating, thyroid disease, seizure disorders or any other serious medical condition (Ando et al. 2022; Ganesh et al. 2019; Brinker 2010; HC 2009; Eccles 2006; Jorge et al. 2006; Bensky et al. 2004; Williamson 2003; Blumenthal et al. 2000; Mills and Bone 2000; Carruthers-Czyzewski 1996). Contraindication(s) Do not use with a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug (US FDA 2022; Brinker 2010; Eccles 2006; Mills and Bone 2005; Blumenthal et al. 2000; Carruthers-Czyzewski 1996). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience severe headache, confusion, visual changes/changes in vision, nervousness, dizziness, sleeplessness, difficulty or pain when urinating or allergic reactions (Ando et al. 2022; Chen 2022; US FDA 2022; Gewirtz et al. 2021; Hinduja 2020; Patel et al. 2020; Pilato 2020; Ducros 2012; Legriel et al. 2021; Mills and Bone 2005; Bensky et al. 2004; Blumenthal et al. 2000; Dickerson et al. 1978). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if any new symptoms appear. 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . All products (information for industry; not for labelling) To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023). 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Ando Y, Ono Y, Sano A, Fujita N, Ono S. Posterior Reversible Encephalopathy Syndrome: A Review of the Literature. Intern Med. 2022;61(2):135-141. Bensky D, Clavey S, Stoger E. Gamble A. Chinese Herbal Medicine: Materia Medica, 3rd edition. Seattle (WA): Eastland Press; 2004. Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. 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Agency; 2009. Mizoguchi H, Wilson A, Jerdack GR, Hull JD, Goodale M, Grender JM, Tyler BA. Efficacy of a single evening dose of syrup containing paracetamol, dextromethorphan hydrobromide, doxylamine succinate and ephedrine sulfate in subjects with multiple common cold symptoms. International Journal of Clinical Pharmacology and Therapeutics 2007;45(4):230-236. Salem CB, Slim R, Denguezli M, Sriha B, Hmouda H, Bouraoui K. Pseudoephedrine-induced acute generalized exanthematous pustulosis. The International Society of Dermatology 2008;47:418-419. Slodki SJ, Montgomery CA. Clinical comparison of oxymetazoline and ephedrine in nasal congestion. Current Therapeutic Research, Clinical and Experimental 1965;7:19-22. Theoharides TC. Sudden death of a healthy college student related to ephedrine toxicity from a ma huang-containing drink. Journal of Clinical Psychopharmacology 1997;17(5):437-439. White LM, Gardner SF, Gurley BJ, Marx MA, Wang PL, Estes M. Pharmacokinetics and cardiovascular effects of ma huang (Ephedra sinica) in normotensive adults. The Journal of Clinical Pharmacology 1997;37:116-122. Whitehouse AM, Duncan JM. Ephedrine psychosis rediscovered. British Journal of Psychiatry 1987;150:258-261. Wingert WE, Mundy LA, Collins GL, Chmara ES. Possible role of pseudoephedrine and other over-the-counter cold medications in the deaths of very young children. Journal of Forensic Science 2007;52(2):487-490. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away (US FDA 2022; HC 2009).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last for more than 7 days (US FDA 2022).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms are accompanied by a high fever that lasts longer than 3 days, the production of thick yellow/green phlegm, rash or a persistent headache.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; CRN 2000; Carruthers-Czyzewski 1996; Mortimer 1977).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking any other cough and cold or weight control medications or prescription drugs, or products which contain caffeine or ephedrine (Brinker 2010; HC 2009; Mills and Bone 2005; Greenway et al. 2004; Naik and Freudenberger 2004).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have asthma, diabetes, glaucoma, heart disease, high blood pressure, kidney disease, difficulty urinating, thyroid disease, seizure disorders or any other serious medical condition (Ando et al. 2022; Ganesh et al. 2019; Brinker 2010; HC 2009; Eccles 2006; Jorge et al. 2006; Bensky et al. 2004; Williamson 2003; Blumenthal et al. 2000; Mills and Bone 2000; Carruthers-Czyzewski 1996). Contraindication(s) Do not use with a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug (US FDA 2022; Brinker 2010; Eccles 2006; Mills and Bone 2005; Blumenthal et al. 2000; Carruthers-Czyzewski 1996). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience severe headache, confusion, visual changes/changes in vision, nervousness, dizziness, sleeplessness,

difficulty or pain when urinating or allergic reactions (Ando et al. 2022; Chen 2022; US FDA 2022; Gewirtz et al. 2021; Hinduja 2020; Patel et al. 2020; Pilato 2020; Ducros 2012; Legriel et al. 2021; Mills and Bone 2005; Bensky et al. 2004; Blumenthal et al. 2000; Dickerson et al. 1978).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if any new symptoms appear.

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 Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information
Source ingredient(s)		
(1S,2S)-2-Methylamino-1-phenylpropan-1-ol (Pseudoephedrine)	Pseudoephedrine	Pseudoephedrine hydrochloride