Pseudoephedrine for children 6-11 years

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PSEUDOEPHEDRINE Children 6-11 years (PDF Version - 81 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. To mitigate the potential risk to the health of children, it is recommended that child resistant packaging/containers be used as described in Sections C.01.001(2) to (4), and subsection C.01.031(1) (a) (i) of the Food and Drug Regulations (JC 2024a). Compliance with Precursor Control Regulations: The Precursor Control Regulations (PCR) (JC 2024b) 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 names(s) Common names(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 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 1980). Note: The above usages 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) Children 6 to 11 years Quantity(ies) 30 - 120 milligrams pseudoephedrine per day; Not to exceed 30 milligrams per single dose (US FDA 2022; HC 2009; Simons et al. 1996; Dickerson et al. 1978). Direction(s) for use Give a single dose every 4-6 hours, up to 4 times per day (US FDA 2022; HC 2009). Do not give with any other cough and cold medications since harm may occur (HC 2009). Duration(s) of use Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (HC 2009; US FDA 2004). 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). 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). 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 the child is taking any other medications including 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 the child has asthma, diabetes, glaucoma, heart disease, high blood pressure, kidney disease, thyroid disease, or 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; Simons et al. 1996; Lambert 1987). Contraindication(s) Do not use in a child who is taking 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). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if the child experiences 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 Product 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. 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Available from: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-97.html JC 2024b: Justice Canada. 2023. Precursor Control Regulations. Part 1 – Class A Precursors. Ottawa (ON) Department of Justice Canada. [Accessed 2025 April 7]. Available from: http://laws-lois.justice.gc.ca/eng/regulations/SOR-2002-359/index.html Jorge S, Lopes JA, De Almeida E, Martins Prata M. Encefalopatía posterior reversible [Posterior reversible encephalopathy syndrome (PRES) and chronic kidney disease]. Nefrologia. 2007;27(5):650 (Spanish). Lambert

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MEDICINAL INGREDIENT(S)

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

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).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).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 the child is taking any other medications including 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 the child has asthma, diabetes, glaucoma, heart disease, high blood pressure, kidney disease, thyroid disease, or 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; Simons et al. 1996; Lambert 1987). Contraindication(s) Do not use in a child who is taking 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). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if the child experiences 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 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 Product Directorate (NNHPD) Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in the NHPID.

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