Ephedrine, L-

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ï»¿ Ephedrine, L- 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 - 36 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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 ephedrine 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 July 31, 2018 Table 1. Proper name(s), Common name(s), Source material(s) Proper name(s) Common name(s) Source material(s) Common name(s) (1R,2S)-2-Methylamino-1-phenylpropan-1-ol (alphaR)-alpha-[(1S)-1-(Methylamino)ethyl]-benzenemethanol [R-(R*,S*)]-alpha-[1-(Methylamino)ethyl]-benzenemethanol l -Ephedrine l -Ephedrine Ephedrine l -Ephedrine l -Ephedrine hydrochloride l -Ephedrine sulfate References: Proper names: NLM 2018, O'Neil et al. 2009, USP32 2009; Common names: NLM 2018, O'Neil et al. 2009, USP32 2009; Source materials: NLM 2018, O'Neil et al. 2009. Route(s) 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 form 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) (Mills and Bone 2005; Hoffman 2003; Williamson 2003; Blumenthal et al. 2000; BHP 1983). Dose(s) Subpopulation(s) Adolescents 12 to 17 years and adults 18 years and older Quantity(ies) 8-32 milligrams l-Ephedrine per day; Not to exceed 8 milligrams per single dose (HC 2007; US FDA 2004; HC 2003; Pickup et al. 1976). Direction(s) for use No statement required. Duration 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 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 (Hackman et al. 2006; Kuczkowski 2006; Mills and Bone 2005; Coffey et al. 2004; Greenway et al. 2004; Haller et al. 2004; Hoffman 2003; Boozer et al. 2002; Boozer et al. 2001; Brinker 2001; Kalman et al. 2000). 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 (Hackman et al. 2006; Mills and Bone 2005; Naik and Freudenberger 2004; Boozer et al. 2002; Boozer et al. 2001). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking other products containing caffeine, ephedrine, phenylpropanolamine or pseudoephedrine (Brinker 2018; Hackman et al. 2006; Mills and Bone 2005; Naik and Freudenberger 2004; Boozer et al. 2002; Brinker 2001; Haller and Benowitz 2000; Kalman et al. 2000). 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 (Hackman et al. 2006; Mills and Bone 2005; Bensky et al. 2004; Coffey et al. 2004; Greenway et al. 2004; Haller et al. 2004; Hioki et al. 2004; Hoffman

2003; Williamson 2003; Boozer et al. 2002; Boozer et al. 2001; Brinker 2001; Blumenthal et al. 2000; Kalman et al. 2000; BHP 1983). Contraindication(s) Do not use this product if you are taking, or have taken monoamine oxidase inhibitors in the past two weeks (Brinker 2018; Greenway et al. 2004; Hoffman 2003; Brinker 2001; Blumenthal et al. 2000; Kalman et al. 2000; Dingemanse et al. 1996; Dawson et al. 1995; Elis et al. 1967). 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; Mehendale et al. 2004; Shekelle et al. 2003; Boozer et al. 2001; Blumenthal et al. 2000; McGuffin et al. 1997; Astrup et al. 1992). 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 specifications outlined in the NHPID. References cited Astrup, A., Buemann, B., Christensen, N. J., Toubro, S., Thorbek, G., Victor, O. J., Quaade, F. 1992. The effect of ephedrine/caffeine mixture on energy expenditure and body composition in obese women. Metabolism 41(7):686-688. Bensky D, Clavey S, Stoger E. Gamble A. 2004. Chinese Herbal Medicine: Materia Medica 3rd Edition. Seattle (WA): Eastland Press. BHP 1983: British Herbal Medicine Association (BHMA) Scientific Committee. 1983. British Herbal Pharmacopoeia 1983. Bournemouth (GB): British Herbal Medicine Association. 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DOSAGE FORM(S)

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

STORAGE CONDITION(S)

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 specifications outlined in the NHPID.

Proper name(s)	Common name(s)	Source material(s)
Common name(s)		
(1R,2S)-2-Methylamino-1-phenylpropan-1-ol	[illegible]	[illegible]