

Ephedra

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EPHEDRA - EPHEDRA SINICA 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 - X 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 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 2019) 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 ephedra, 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 August 5, 2019 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) Proper name(s) Part(s) Preparation Ephedra sinica Cao ma-huang Chinese ephedra Chinese joint-fir Ephedra Ma-huang Ephedra sinica Branch Branchlet Stem Dried References: Proper name: USDA 2019, McGuffin et al. 2000; Common names: USDA 2019, Brinker 2010, Blumenthal et al. 2000, McGuffin et al. 2000; Source materials: Hoffman 2003, DerMarderosian and Beutler 2002, Blumenthal et al. 2000, Liguio et al. 1999. 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 in Herbal Medicine as a decongestant/to relieve nasal congestion (due to hay fever/allergic rhinitis/allergies/sinusitis/the common cold/flu) (Mills and Bone 2005; Mehendale et al. 2004; Hoffman 2003; Blumenthal et al. 2000; BHP 1983). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Standardized extracts Extract providing 8 - 32 milligrams of l-Ephedrine, per day; Not to exceed 8 milligrams of l-Ephedrine per single dose; and Quantity crude equivalent 400 - 1,600 milligrams of dried branchlet and/or branch, and/or stem, per day (HC 2008; HC 2007; MHRA 2005; US FDA 2004; Pickup et al. 1976). Direction(s) for use No statement required. 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. 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 2010; Hackman et al. 2006; Mills and Bone 2005; Greenway et al. 2004; 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 a cardiovascular disease, diabetes, difficulty in urination due to prostate enlargement, glaucoma, thyroid problems, seizure disorders, or pre-existing psychiatric

conditions (Brinker 2010; 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; Mehendale 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 (MAO) inhibitors in the past two weeks (Brinker 2010; 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, tremors, severe headache, insomnia, loss of appetite, nausea, rapid heartbeat, shortness of breath, and/or disturbance of urination (Bensky et al. 2004; Mehendale et al. 2004; Shekelle et al. 2003; Boozer et al. 2001; 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 requirements 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. 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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. Storage conditions Store protected from light and moisture (BP 2009; USP 32 2009; Ph. Eur. 2007).

DOSAGE FORM(S)

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.

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 2010; Hackman et al. 2006; Mills and Bone 2005; Greenway et al. 2004; 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 a cardiovascular disease, diabetes, difficulty in urination due to prostate enlargement, glaucoma, thyroid problems, seizure disorders, or pre-existing psychiatric conditions (Brinker 2010; 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; Mehendale 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 (MAO) inhibitors in the past two weeks (Brinker 2010; 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, tremors, severe headache, insomnia, loss of appetite, nausea, rapid heartbeat, shortness of breath, and/or disturbance of urination (Bensky et al. 2004; Mehendale et al. 2004; Shekelle et al. 2003; Boozer et al. 2001; 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).

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 requirements outlined in the NHPID.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		
Ephedra sinica	Cao ma-huangChinese ephedraChinese joint pineEphedra sinica	Ephedra sinicaCao ma-huang	BranchBranchletStem	Dried