

Elder - Sambucus

Source: <https://webprod.hc-sc.gc.ca/nhp/ids/bdipsn/atReq?atid=elder.sureau&lang=eng>

Extracted: 2025-08-26T06:32:31.088190

ELDER - SAMBUCUS 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 - 104 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. Date July 1, 2019 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 material(s) Part(s) Preparation(s) Sambucus nigra subsp. nigra Black elder European elder Sambucus nigra subsp. nigra Flower Fruit Dry Sambucus nigra subsp. canadensis American elder Canadian elder Sweet elder Sambucus nigra subsp. canadensis References: Proper names: USDA 2019a,b, McGuffin et al. 2000; Common names: NHPID 2019; Source information: EMA 2018, Godfrey and Saunders 2010, Hoffman 2003. 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 by age group: Children 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/ liquid preparations (Giaccoia et al. 2008; EMA/CHMP 2006). Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giaccoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: 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) Adults 18 years and older Flower (Traditionally) used in Herbal Medicine to promote sweating (diaphoretic) to help relieve fever (in cases of common colds, flus) (Godfrey and Saunders 2010; Bone 2003; Hoffman 2003; WHO 2002; BHC 1992; BHP 1983; Grieve 1931; Sayre 1917; Felter and Lloyd 1898). (Traditionally) used in Herbal Medicine to help relieve symptoms of colds and flus (such as coughs, sore throat and mucus buildup (catarrh) of the (upper) respiratory tract) (Godfrey and Saunders 2010; Barnes et al. 2007; Bone 2003; Hoffman 2003; WHO 2002; BHP 1983; Grieve 1931). Used in Herbal Medicine to help relieve nasal congestion and discharge associated with sinusitis, hay fever/allergic rhinitis (Godfrey and Saunders 2010; Barnes et al. 2007; Bone 2003; Hoffman 2003). (Traditionally) used in Herbal Medicine as a diuretic (Winston and Kuhn 2008; Barnes et al. 2007; Williamson 2003; BHC 1992; Felter 1922; Culbreth 1927; Fyfe 1903). (Traditionally) used in Herbal Medicine (as an alternative) to help remove accumulated waste products via the kidneys, skin and mucus membranes (Williamson 2003; Tilgner 1999; Felter 1922; Culbreth 1921; Fyfe 1903; Felter and Lloyd 1898). The following combined use(s) or purpose(s) is/are also acceptable: Used in Herbal Medicine to help relieve symptoms of colds and flus (such as coughs, sore throat and mucus buildup (catarrh) of the (upper) respiratory tract) and to help relieve nasal congestion and discharge associated with sinusitis, hay fever/allergic rhinitis (Godfrey and Saunders 2010; Barnes et al. 2007; Bone 2003; Hoffman 2003; WHO 2002; BHP 1983; Grieve 1931). Fruit (Traditionally) used in Herbal Medicine to promote sweating (diaphoretic) to help relieve fever (in cases of common colds, flus) (Winston and Kuhn 2008; Hoffman 2003; Shook 1992; Grieve 1931; Remington et al. 1918). (Traditionally) used in Herbal Medicine to help relieve symptoms of colds and flus (such as coughs, sore throat and mucus buildup (catarrh) of the (upper) respiratory tract) (Winston and Kuhn 2008; Hoffman 2003; Tillotson 2001; Shook 1992). (Traditionally) used in Herbal Medicine to help relieve joint pain associated with conditions such as arthritis (Godfrey and Saunders 2010; Hoffman 2003; Tilgner 1999; Grieve 1931; Remington et al. 1918). (Traditionally) used in Herbal Medicine as a diuretic (Hoffman 2003; Shook 1992; Fyfe 1903). (Traditionally) used in Herbal Medicine (as an alternative) to help remove accumulated waste products via the kidneys, skin and mucus membranes (Tilgner 1999; Shook 1992; Grieve 1931; Remington et al. 1918; Fyfe 1903). Source of/Provides antioxidants (Youdim et al. 2004; Abuja et al. 1998). The following combined use(s) or purpose(s) is/are also acceptable: (Traditionally) used in Herbal Medicine to promote sweating (diaphoretic) to help relieve fever (in cases of the common cold, flus) and to help relieve symptoms of colds and flus (such as coughs, sore throat

and mucus buildup (catarrh) of the (upper) respiratory tract) (Winston and Kuhn 2008; Hoffman 2003; Tillotson 2001; Shook 1992; Grieve 1931; Remington et al. 1918). Children 2-11 years and Adolescents 12-17 years Flower and/or Fruit (Traditionally) used in Herbal Medicine to promote sweating (diaphoretic) to help relieve fever (in cases of common colds, flus) (Godfrey and Saunders 2010; Winston and Kuhn 2008; Bone 2003; Hoffman 2003; WHO 2002; Shook 1992; BHC 1992; BHP 1983; Grieve 1931; Remington et al. 1918; Sayre 1917; Felter et Lloyd 1898). (Traditionally) used in Herbal Medicine to help relieve symptoms of colds and flus (such as coughs, sore throat and mucus buildup (catarrh) of the (upper) respiratory tract) (Godfrey and Saunders 2010; Winston and Kuhn 2008; Barnes et al. 2007; Bone 2003; Hoffman 2003; WHO 2002; Tillotson 2001; Shook 1992; BHP 1983; Grieve 1931). The following combined use(s) or purpose(s) is/are also acceptable: (Traditionally) used in Herbal Medicine to promote sweating (diaphoretic) to help relieve fever (in cases of the common cold, flus) and to help relieve symptoms of colds and flus (such as coughs, sore throat and mucus buildup (catarrh) of the (upper) respiratory tract) (Godfrey and Saunders 2010; Winston and Kuhn 2008; Barnes et al. 2007; Bone 2003; Hoffman 2003; WHO 2002; Tillotson 2001; Shook 1992; BHP 1983; Grieve 1931; Remington et al. 1918; Sayre 1917; Felter et Lloyd 1898). Flower Used in Herbal Medicine to help relieve nasal congestion and discharge associated with sinusitis, hay fever/allergic rhinitis (Godfrey and Saunders 2010; Barnes et al. 2007; Bone 2003; Hoffman 2003). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) As specified below. Quantity(ies) Flower Methods of preparation: Dry, Powder, Non-Standardized Ethanollic Extracts (Dry extract, Tincture, Fluid extract) Table 2. Dose information for dried flower presented as grams per day Use(s) or purpose(s) Subpopulation(s) Dried flowers (grams/day) Minimum Maximum Diaphoretic Sinusitis, hay fever Symptoms of colds and flus Children 1 2-4 years 0.25 2.5 5-9 years 0.375 3.75 Children 1 10-11 years 0.75 7.5 Adolescents 1 12-13 years 0.75 7.5 Adolescents 1 14-17 years 1.5 15 Diaphoretic Symptoms of colds and flus Sinusitis, hay fever Diuretic Alterative Adults 2 18 years and older 1.5 15 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of Elder spp. in children and adolescents is supported by the following references: McIntyre 2005; Bove 2001; Gladstar 1999. 2 Adult dose supported by the following references: Hoffman 2003 Williamson 2003;WHO 2002; BHC 1992. Method of preparation: Infusion Table 3. Dose information for dried flower presented as grams per day Use(s) or purpose(s) Subpopulation(s) Dried flowers (grams/day) Minimum Maximum Diaphoretic Sinusitis, hay fever Symptoms of colds and flus Children 1 2-4 years 1 2.5 5-9 years 1.5 3.75 Children 1 10-11 years 3 7.5 Adolescents 1 12-13 years 3 7.5 Adolescents 1 14-17 years 6 15 Alterative Diaphoretic Diuretic Sinusitis, hay fever Symptoms of colds and flus Adults 2 18 years and older 6 15 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of Elder spp. in children and adolescents is supported by the following references: McIntyre 2005; Bove 2001; Gladstar 1999. 2 Adult dose supported by the following references: Hoffman 2003 Williamson 2003;WHO 2002; BHC 1992. Fruit Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) Table 4. Dose information for dried fruit presented as grams per day Use(s) or purpose(s) Subpopulation(s) Dried fruit (grams/day) Minimum Maximum Diaphoretic Symptoms of colds and flus Children 1 2-4 years 0.217 3 5-9 years 0.325 4.5 Children 1 10-11 years 0.65 9 Adolescents 1 12-13 years 0.65 9 Adolescents 1 14-17 years 1.3 18 Alterative Diaphoretic Diuretic Joint pain Symptoms of colds and flus Adults 2 18 years and older 1.3 18 Antioxidants Adults 3 18 years and older - 18 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of Sambucus spp. in children and adolescents is supported by the following references: McIntyre 2005; Bove 2001; Gladstar 1999. 2 Adult dose supported by the following references: Winston and Kuhn 2008; Tillotson 2001; Fyfe 1903. 3 Adult dose supported by the following reference: Winston and Kuhn 2008. Direction(s) for use No statement required. Duration(s) of Use Diuretic For occasional use only (APhA 2002; CPhA 2002). All other products No statement required. Risk Information Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Diaphoretic; Symptoms of colds, flus; Sinusitis, hay-fever; Joint pain Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occur (Forster-Waldl et al. 2003). Products without diuretic claim Diuretic effect may occur (Bradley 1992; Winston and Kuhn 2008; Barnes et al. 2007; Hoffman 2003). 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 (NHPR). 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 Abuja PM, Murkovic M., Pfannhauser W. Antioxidant and Prooxidant Activities of Elderberry (Sambucus nigra) Extract in Low-Density Lipoprotein Oxidation. Journal of Agricultural and Food

Chemistry 1998;46(10):4091-4096. APhA 2002: Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care. 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Artz S.A., Paes I.C., Faloon W.W. Hypokalemia-induced hepatic coma in cirrhosis. Occurrence despite neomycin therapy. Gastroenterology 1966; 51(6):1046. Barnes J, Anderson LA, Philipson JD. Herbal Medicines. 3rd edition. London (GB): The Pharmaceutical Press; 2007. BHC 1992: Bradley PR, editor. British Herbal Compendium Volume 1: A Handbook of Scientific Information on Widely Used Plant Drugs-Companion to Volume 1 of the British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1992. BHP 1983: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1983. Bone K. A Clinical Guide to Blending Liquid Herbs: Herbal Formulations for the Individual Patient. St. Louis (MI): Churchill Livingstone; 2003. Bove M. An Encyclopedia of Natural Healing for Children and Infants. 2nd edition. Toronto (ON): McGraw-Hill; 2001. Carlsen J.E., Kober L., Torp-Pedersen C., Johansen P. Relation between dose of bendroflumazide, antihypertensive effect and adverse biochemical effects. British Medical Journal 1990; 300(6730): 975. CPhA 2002: Canadian Pharmacists Association. Patient Self-Care. Helping Patients Make Therapeutic Choices. Ottawa (ON): Canadian Pharmacists Association; 2002. Culbreth DMR. A Manual of Materia Medica and Pharmacology [Internet] 7th edition; 1927. Abridged and edited; herbs and botanicals in use today. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2019 May 8]. Available from: <http://www.swsbm.com/ManualsOther/Culbreth.html> EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. Adopted September 2006. EMA/CHMP/PEG/194810/2005. [Accessed on 2019 June 12]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf EMA 2018: Sambuci flos. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (CHMP). [Accessed 2019 June 12]. Available from: <https://www.ema.europa.eu/en/medicines/herbal/sambuci-flos> Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original]. Felter HW, Lloyd JU. King's American Dispensatory. Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Förster-Waldl E, Marchetti M, Schöll I, Focke M, Radauer C, Kinaciyan T., Nentwich I, Jäger S, Schmid ER, Boltz-Nitulescu G, Scheiner O, Jensen-Jarolim E. Type I allergy to elderberry (*Sambucus nigra*) is elicited by a 33.2 kDa allergen with significant homology to ribosomal inactivating proteins. Clinical and Experimental Allergy. 2003;33(2):1703-1710. Fyfe JW. The Essentials of Modern Materia Medica and Therapeutics [Internet] Eclectic Manual #6; 1903. Abridged; herbal material only. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2019 May 8]. Available from: <http://www.swsbm.com/ManualsOther/Fyfe.html> Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. Clinical Therapeutics 2008; 30(11):2097-2101. Gladstar R. Herbal Remedies for Children's Health. North Adams (MA): Storey Publishing; 1999 Godfrey A, Saunders PR, Barlow K, Gilbert C, Gowan M, Smith F. Principles and Practices of Naturopathic Botanical Medicine. Volume 1: Botanical Medicine Monographs. Toronto (ON): CCNM Press; 2010. Grieve M. A Modern Herbal. Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce. 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. McIntyre A. Herbal Treatment of Children: Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Mujais S.K., Katz A.L. Potassium deficiency in the Kidney: Physiology and Pathophysiology, Seldin D.W., Giebisch G (Eds), Lippincott Williams and Wilkins, 2000. P1615. Remington JP, Woods HC, editors. The Dispensary of the United States of America [Internet] 20th edition; 1918. Abridged; botanicals only. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2019 May 8]. Available from: <http://www.swsbm.com/Dispensary/USD-1918-complete.pdf> Sayre LE. A Manual of Organic Materia Medica and Pharmacognosy [Internet] 4th edition. Philadelphia (PA): P. Blakiston's Son & Co.; 1917. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2019 May 8]. Available from: <http://www.swsbm.com/SayreMM/SayreMM.html> Shook EE. Advanced Treatise in Herbology. Banning (CA): Enos Publishing Co; 1992. Tilgner S. Herbal Medicine from the Heart of the Earth. Creswell (OR): Wise Acre Press; 1999. Tillotson AK. The One Earth Herbal Sourcebook. New York (NY): Kensington Publishing Corp.; 2001. USDA 2019a: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [online database]. 2019. *Sambucus nigra* (L). National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 August 15]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> USDA 2019b: United

States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [online database].2019. [Sambucus nigra L. subsp. canadensis (L.) Bolli. National Germplasm Resources Laboratory, Beltsville (MD) [Accessed 2019 May 8]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 2. Geneva (CH): World Health Organization; 2002. Williamson EM. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003. Winston D and Kuhn MA. Herbal Therapy & Supplements A Scientific and Traditional Approach. Philadelphia (PA): Lippincott Williams & Wilkins; 2008. Youdim KAU, Martin A, Josepha JA. Incorporation of the elderberry anthocyanins by endothelial cells increases protection against oxidative stress. Free Radical Biology and Medicine 2000;29(1):51-60. References Reviewed Barak V, Halperin T, Kalickman I. The effect of Sambucol, a black-berry-based natural product, on the production of human cytokines: I. Inflammatory cytokine. 2001;12(2): Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Newton (MA): Integrative Medicine Communications; 2000. Brinker F. The Toxicology of Botanical Medicines. Sandy (OR): Eclectic Medical Publications; 2000. Cook WH. The Physio-Medical Dispensatory: A Treatise on Therapeutics, Materia Medica, and Pharmacy, in Accordance with the Principles of Physiological Medication. Cincinnati (OH): WH Cook; 1869. Reprint version by Medical Herbalism: Journal for the Clinical Practitioner. [Accessed 2014 August 15]. Available from: <http://medherb.com/cook/home.htm> Duke JA, Bogenschutz-Godwin MJ, duCellier J, Duke PK. Handbook of Medicinal Herbs.2nd edition. Boca Raton (FL): CRC Press; 2002. EMA 2014: EMA/CHMP/44208/2012 Assessment report on Sambucus nigra L., fructus. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (CHMP). [Accessed 2014 August 15]. Available from: <http://www.ema.europa.eu> Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. Second Edition. Boca Raton (FL): Taylor and Francis Group; 2013. Hill J. The Family Herbal. Bungay: Printed and Published by C. Brightly, and T. Kinnersley; 1812. Reprint version by Henriette Kress 2011-2014: Henriette's Herbs. [Accessed 2014 August 15]. Available from: <http://www.henriettes-herb.com/eclectic/hill/index.html> Inami O, Tamura I, Kikuzaki H, Nakatani N. Stability of Anthocyanins of Sambucus canadensis and Sambucus nigra, Journal of Agriculture and Food Chemistry 1996;44:3090-3096. Jellin JM, editor. Pharmacist's Letter/Prescriber's Letter Natural Medicines Comprehensive Database [Internet]. Stockton (CA): Therapeutic Research Faculty; 1995-2014. [American elder; Accessed 2014 August 15]. Available from: <http://naturaldatabase.therapeuticresearch.com/nd/Search.aspx?cs=CEPDA&s=ND&pt=100&id=942&fs=ND&searchid=47853478> Jourdan AJL. Pharmacopée universelle, ou conspectus des pharmacopées, Volume 2. [Internet] Seconde édition; 1828. [Accessed 2014 August 15]. Available from: <http://books.google.ca/books?id=5F6CI5Fy-MIC&printsec=frontcover&dq=jourdan+pharmacopee+universelle+volume+2&hl=en&sa=X&ei=YEbuU8fOF8iNyATI0YKQAw&ved=0CBMQ6AEwAA#v=onepage&q=jourdan%20pharmacopee%20universelle%20volume%202&f=false> Lee J and Finn CE. Anthocyanins and other polyphenolics in American elderberry (Sambucus canadensis) and European elderberry (S. nigra) cultivars. Journal of the Science of Food and Agriculture 2007;87:2665-2675. Murkovic M, Abuja PM, Bergmann AR, Zirngast A, Adam U, Winklhofer-Roob BM, Toplak H. Effects of elderberry juice on fasting and postprandial serum lipids and low-density lipoprotein oxidation in healthy volunteers; a randomized, double-blind, placebo-controlled study. European Journal of Clinical Nutrition 2004;58:244-249. Nakajima J-I, Tanaka I, Seo S, Yamazaki M, Saito K. LC/PDA/ESI-MS Profiling and Radical Scavenging Activity of Anthocyanins in Various Berries. Journal of Biomedicine and Biotechnology 2004;5:241-247. Scudder JM. Specific Medication and Specific Medicines. Cincinnati (OH); Wiltach, Baldwin & Co. 1870. Reprint version by Henriette Kress 2011-2014: Henriette's Herbs. [Accessed 2014 August 15]. Available from: <http://www.henriettes-herb.com/eclectic/spec-med/sambucus.html> Vlachojannis JE, Cameron M, Chrubasik S. A systematic review on the sambuci fructus effect and efficacy profiles. Phytotherapy Research 2010;24(1):1-8. Wichtl M, Anton R, éditeurs. Plantes thérapeutiques: Tradition, pratique officinale, sciences et thérapeutique. 2e édition. Paris (FR): Lavoisier; 2003. Zafra-Stone S, Yasmin T, Bachi M, Chatterjee A. Berry anthocyanins as novel antioxidants in human health and disease prevention. Molecular Nutrition and Food Research 2007;51:576-683. Zakay-Rones Z, Thom E, Wollan T, Wadstein J. Randomized study of the efficacy and safety of oral elderberry extract in the treatment of influenza A and B virus infections. Journal of International Medical Research 2004;32:132-140. 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 the Natural Health Products Regulations (NHPR).

DOSAGE FORM(S)

Acceptable dosage forms by age group: Children 2 years:The acceptable dosage forms are limited to emulsion/suspension and solution/ liquid preparations (Giacchia et al. 2008; EMA/CHMP 2006). Children 3-5 years:The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacchia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: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) All products Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Diaphoretic; Symptoms of colds, flu; Sinusitis, hay-fever; Joint pain Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occur (Forster-Waldl et al. 2003). Products without diuretic claim Diuretic effect may occur (Bradley 1992; Winston and Kuhn 2008; Barnes et al. 2007; Hoffman 2003).

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 (NHPR).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

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

Proprietary name(s)	Common name(s)	Source information	
Source material(s)	Part(s)	Preparation(s)	
Sambucus nigra subsp. nigra	Black elderEuropean elder	Sambucus nigra subsp. nigra	FlowerFruit
Sambucus nigra subsp. canadensis	American elderCanadian elderSweet elder	Sambucus nigra subsp. canadensis	

Dried flowers (grams/day)										
2-4 years	0.25	2.5	5-9 years	0.375	3.75	Children1	10-11 years	0.75	7.5	Adolescents1
3.75										
0.75	7.5									
18 years and older	1.5	15								

	Dried flowers (grams/day)									
	2-4 years	1	2.5	5-9 years	1.5	3.75	Children1	10-11 years	3	7.5 Adolescents1
	3.75									
	3	7.5								
	18 years and older	6	15							

	Dried fruit (grams/day)									
	2-4 years	0.217	3	5-9 years	0.325	4.5	Children1	10-11 years	0.65	9 Adolescents1
	4.5									
	0.65	9								
	18 years and older	1.3	18							
	18 years and older	-	18							