Health Canada Santé Canada

NATURAL HEALTH PRODUCT

ELDER – *SAMBUCUS*

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 (Giacoia 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 (Giacoia 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 alterative) 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 alterative) 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 Ethanolic 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 flower (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
▶ Alterative ▶ Diaphoretic ▶ Diuretic ▶ Sinusitis, hay fever ▶ Symptoms of colds and flus	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: Winston and Kuhn 2008; Bone 2003; WHO 2002; BHC 1992; Fyfe 1903.

Method of preparation: Infusion

Table 3. Dose information for dried flower presented as grams per day

Use(s) or purpose(s)	Subpopulation(s)		Dried flower (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.

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