

## 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 the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** July 18, 2017

#### Proper name(s) and Common name(s):

Proper name	Common Name	References
<i>Sambucus nigra</i> L. subsp. <i>nigra</i> [Adoxaceae (Caprifoliaceae)]	<ul style="list-style-type: none"> <li>▶ European elder</li> <li>▶ Black elder</li> </ul>	McGuffin et al. 2000; USDA 2014a
<i>Sambucus nigra</i> L. subsp. <i>canadensis</i> (L.) R. Bolli [Adoxaceae (Caprifoliaceae)]	<ul style="list-style-type: none"> <li>▶ American elder</li> <li>▶ Canadian elder</li> </ul>	USDA 2014b; McGuffin et al. 2000

#### Note

- ▶ *Sambucus nigra* is a taxonomic synonym of *Sambucus nigra* L. subsp. *nigra*.
- ▶ *Sambucus canadensis* is a taxonomic synonym of *Sambucus nigra* subsp. *canadensis*.

#### Source material(s):

- ▶ Flower (Godfrey and Saunders 2010; EMEA 2008; Hoffman 2003)
- ▶ Fruit (Godfrey and Saunders 2010; Hoffman 2003)

#### Route(s) of administration:

Oral



## Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms, such as bars, chewing gums or beverages.

Dosage forms by age group:

- **Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults  $\geq$  18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

## Use(s) or Purpose(s):

Adults ( $\geq$  18 years)

### *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 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).

### *Fruit (berry)*

- ▶ (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 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).
- ▶ Provides antioxidants (Youdim et al. 2004; Abuja et al. 1998).

## Children and adolescents

### *Flower and/or Fruit (berry)*

- ▶ (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 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).

### *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**

A claim for traditional use must include the term “Herbal Medicine”.

### **Dose(s):**

### **Subpopulation(s)**

Adults (≥ 18 years), Adolescents (14-17 years), Adolescents (10-13 years), Children (5-9 years), Children (2-4 years)

### **Quantity(ies)**

### *Flower*

Table 1: Dosing information for Flower. Preparations: Dry, Powder, Non standardized ethanolic extracts (extract dry, tincture, fluid extract)

Use(s) or purpose(s)	Subpopulations		Dried flowers (g/day)	
			Minimum	Maximum
Diaphoretic; Symptoms of colds and flus; Sinusitis, hay fever	Children <sup>1</sup>	2-4 y	0.25	2.5
		5-9 y	0.375	3.75
	Adolescents <sup>1</sup>	10-13 y	0.75	7.5
		14-17 y	1.5	15
Diaphoretic; Symptoms of colds and flus; Sinusitis, hay fever; Diuretic; Alterative	Adults <sup>2</sup>	≥ 18 y	1.5	15

<sup>1</sup> 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.

<sup>2</sup> Adult dose supported by the following references: Winston and Kuhn 2008; Bone 2003; WHO 2002; BHC 1992; Fyfe 1903.

Table 2: Dosing information for Flower. Preparation: Infusion

Use(s) or purpose(s)	Subpopulations		Dried flowers (g/day)	
			Minimum	Maximum
Diaphoretic; Symptoms of colds and flus; Sinusitis, hay fever	Children <sup>1</sup>	2-4 y	1	2.5
		5-9 y	1.5	3.75
	Adolescents <sup>1</sup>	10-13 y	3	7.5
		14-17 y	6	15
Diaphoretic; Symptoms of colds and flus; Sinusitis, hay fever; Diuretic; Alterative	Adults <sup>2</sup>	≥ 18 y	6	15

<sup>1</sup> 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.

<sup>2</sup> Adult dose supported by the following references: Hoffman 2003; Williamson 2003; WHO 2002; BHC 1992.

### *Fruit (berry)*

**Note:** Preparations from Fresh fruits (berries) are not covered by this monograph.

Table 3: Dosing information for ripe Fruit (berry). Preparations: Dry, Powder, Non standardized extracts (extract dry, tincture, fluid extract, infusion, decoction)

Use(s) or purpose(s)	Subpopulations		Dried, ripe berries (g/day)	
			Minimum	Maximum
Diaphoretic; Symptoms of colds and flus	Children <sup>1</sup>	2-4 y	0.217	3
		5-9 y	0.325	4.5
	Adolescents <sup>1</sup>	10-13 y	0.65	9
		14-17 y	1.3	18
Diaphoretic; Alterative; Diuretic; Symptoms of colds and flus; Joint pain	Adults <sup>2</sup>	≥ 18 y	1.3	18
Antioxidants	Adults <sup>3</sup>	≥ 18 y	-	18

<sup>1</sup> 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.

<sup>2</sup> Adult dose supported by the following references: Winston and Kuhn 2008; Tillotson 2001; Fyfe 1903.

<sup>3</sup> Adult dose supported by the following reference: Winston and Kuhn 2008.

### **Duration 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*

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

*Diaphoretic; Symptoms of colds, flus; Sinusitis, hay-fever; Joint pain*

If symptoms persist or worsen, consult a health care practitioner.

#### **Contraindication(s)**

No statement required.

#### **Known adverse reaction(s)**

##### *All products*

Hypersensitivity (e.g. allergy) can occur, in which case, discontinue use (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:

No statement required.

### 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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