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):

<table>
<thead>
<tr>
<th>Proper name</th>
<th>Common Name</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sambucus nigra L. subsp. nigra [Adoxaceae (Caprifoliaceae)]</td>
<td>European elder ▶ Black elder</td>
<td>McGuffin et al. 2000; USDA 2014a</td>
</tr>
<tr>
<td>Sambucus nigra L. subsp. canadensis (L.) R. Bolli [Adoxaceae (Caprifoliaceae)]</td>
<td>American elder ▶ Canadian elder</td>
<td>USDA 2014b; McGuffin et al. 2000</td>
</tr>
</tbody>
</table>

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 ≥ 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 (≥ 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)
### Table 2: Dosing information for Flower. Preparation: Infusion

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

<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.

### 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)

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

<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: Hoffman 2003 Williamson 2003; WHO 2002; BHC 1992.
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.

**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.

**References cited:**


Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original].


References reviewed:


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.


