

## NATURAL HEALTH PRODUCT

### ANGELICA – *ANGELICA ARCHANGELICA*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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 labels 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** January 26, 2024

#### 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)
<i>Angelica archangelica</i>	<ul style="list-style-type: none"> <li>• Angelica</li> <li>• Angelique</li> <li>• Archangel</li> <li>• European angelica</li> <li>• Garden angelica</li> <li>• Root of the holy ghost</li> <li>• Wild parsnip</li> </ul>	<i>Angelica archangelica</i>	<ul style="list-style-type: none"> <li>• Leaf</li> <li>• Root and rhizome</li> <li>• Seed</li> </ul>

References: Proper name: USDA 2023; Common names: USDA 2023, Brinker 2010, Barnes et al. 2007, Hoffmann 2003, Blumenthal et al. 2000, McGuffin et al. 2000, Felter and Lloyd 1983, Grieve 1971; Source information: Barnes et al. 2007, Bradley 2006, Hoffmann 2003, Blumenthal et al. 2000, Mills 1985, Felter and Lloyd 1983, Grieve 1971.

#### 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 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)

- Traditionally used in Herbal Medicine as an expectorant to help relieve bronchial illness, coughs and colds (Bradley 2006; Hoffmann 2003; Blumenthal et al. 2000; Grieve 1971).
- Traditionally used in Herbal Medicine to aid digestion (stomachic) (Bradley 2006; Hoffmann 2003; Blumenthal et al. 2000; Mills 1985; Grieve 1971).
- Traditionally used in Herbal Medicine to help relieve flatulent dyspepsia (carminative) (Bradley 2006; Hoffmann 2003; Grieve 1971)
- Traditionally used in Herbal Medicine to help relieve feverish conditions by inducing sweating (diaphoretic) (Bradley 2006; Grieve 1971).
- Traditionally used in Herbal Medicine as a diuretic (Barnes et al. 2007; Hoffmann 2003; Mills 1985; Felter and Lloyd 1983).

### Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Traditionally used in Herbal Medicine to aid digestion (stomachic) and help relieve flatulent dyspepsia (carminative)).
- **For multi-ingredient products:**
  - To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Angelica is traditionally used in Herbal Medicine to help relieve feverish conditions by inducing sweating (diaphoretic)).
  - When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

### Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Infusion)

### *Root and Rhizome*

0.3-12 grams dried root and rhizome, per day (Barnes et al. 2007; Bradley 2006; Blumenthal et al. 2000; Mills 1985).

### *Leaf*

0.4-5 grams dried leaf, 3 times per day (BHP 1983).

### *Seed*

1-2 grams dried seed, 3 times per day (Mills 1985).

**\*Note:** Solvents allowed for the method of preparation “Non-standardized extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

### **Direction(s) for use**

No statement required

### **Duration(s) of use**

#### *Diuretic*

For occasional use only (Berardi et al. 2002; CPhA 2002).

#### *Other uses*

No statement required.

### **Risk information**

#### **Caution(s) and warning(s)**

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding** (Brinker 2010; Barnes et al. 2007).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a peptic ulcer** (Brinker 2010; Barnes et al. 2007).
- **When using this product** avoid prolonged exposure to sunlight, ultraviolet light (UV) or UV therapy (Brinker 2010; Barnes et al. 2007; Blumenthal et al. 2000).

### Contraindication(s)

**Do not use if** you are pregnant (Brinker 2010; Barnes et al. 2007; Blumenthal et al. 2000).

### Known adverse reaction(s)

No statement required.

### 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*.

### 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.

### EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
<b>Medicinal ingredient in each capsule</b>	
<i>Angelica archangelica</i> (Angelica) – leaf	XX mg
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Traditionally used in Herbal Medicine as an expectorant to help relieve bronchial illness, coughs and colds</li> <li>• Traditionally used in Herbal Medicine to aid digestion (stomachic)</li> <li>• Traditionally used in Herbal Medicine to help relieve flatulent dyspepsia (carminative)</li> <li>• Traditionally used in Herbal Medicine to help relieve feverish conditions by inducing sweating (diaphoretic)</li> <li>• Traditionally used in Herbal Medicine as a diuretic</li> </ul>	

<b>Warnings</b>
<b>If applicable:</b> <b>Allergens: food allergen, gluten (gluten source), sulphites</b> <b>Contains aspartame</b>
<b>Do not use if you are pregnant.</b>
<b>Ask a health care practitioner before use if:</b> • you are breastfeeding. • you have a peptic ulcer.
<b>Ask a health care practitioner if symptoms persist or worsen.</b>
<b>When using this product</b> avoid prolonged exposure to sunlight, ultraviolet light (UV) or UV therapy.
<b>Directions</b> Adults 18 years and older: • Take X capsule(s), X times a day. <i>Diuretic</i> • For occasional use only.
<b>Other information</b> (Add storage information)
<b>Non-medicinal ingredients</b> List all NMIs
<b>Questions? Call 1-XXX-XXX-XXXX</b>

## References cited

Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3<sup>rd</sup> edition. London (UK): Pharmaceutical Press; 2007.

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, 13<sup>th</sup> edition. Washington (DC): American Pharmaceutical Association; 2002.

BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983.

Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000.

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Brinker F. Herb Contraindications and Drug Interactions, 4<sup>th</sup> edition. Sandy (OR): Eclectic Medical Publications; 2010.

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Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000.

Moerman DE. Native American Ethnobotany. Portland (OR): Timber Press; 1998.

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