

## NATURAL HEALTH PRODUCT

### WILLOW BARK

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

March 28, 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)   | Preparation(s) |
| Willow bark    | Willow bark    | <ul style="list-style-type: none"> <li>• <i>Salix alba</i></li> <li>• <i>Salix daphnoides</i></li> <li>• <i>Salix purpurea</i></li> <li>• <i>Salix x fragilis</i></li> </ul> | <ul style="list-style-type: none"> <li>• Bark</li> <li>• Young branch bark</li> </ul> | Dry            |

References: Proper name: Blumenthal et al. 2000, Bradley 1992; Common name: Blumenthal et al. 2000, Bradley 1992; Source information: USDA 2023, EMA 2017; Wichtl 2004, ESCOP 2003, Blumenthal et al. 2000.

#### 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)

- Used in Herbal Medicine for short-term relief of lower back pain (EMA 2017).
- Used in Herbal Medicine to relieve minor joint pain (due to osteoarthritis) (EMA 2017; ESCOP 2003).
- Used in Herbal Medicine to relieve fever associated with the common cold (EMA 2017).
- Used in Herbal Medicine to relieve headache (EMA 2017).

**Notes:** The above uses can be combined on the product label (e.g., Used in Herbal Medicine to help relieve fever associated with the common cold and headache).

### Dose(s)

#### Subpopulation(s)

Adults 18 years and older

#### Quantity(ies)

**Note:** When ‘decoction’ or ‘infusion’ is listed as an acceptable method of preparation, ‘decoction concentrate’ or ‘infusion concentrate’ is also allowed. It also applies to standardized methods of preparation.

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

3 - 9 grams of dried (young branch) bark per day in divided doses; Not to exceed 3 grams per single dose (EMA 2017; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000)

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Extract providing up to 15% total salicin equivalent to 45 - 240 milligrams of total salicin per day in divided doses; Not to exceed 120 milligrams of salicin per single dose (EMA 2017; WHO 2009; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000)

#### Direction(s) for use

No statement required.

### Duration(s) of use

Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 weeks (Beer and Wegener 2008; Biegert et al. 2004).



## 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 have asthma or peptic ulcer disease (EMA 2017).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you are taking blood thinners or products containing salicylates (e.g., acetylsalicylic acid or non-steroidal anti-inflammatory drugs) (EMA 2017).

### Contraindication(s)

- **Do not use if** you are pregnant or breastfeeding (EMA 2017; Brinker 2010; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000).
- **Do not use if** you are allergic to salicylates (EMA 2017; Brinker 2010; Wichtl 2004, ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000).

### Known adverse reaction(s)

**When using this product** you may experience gastrointestinal discomfort/disturbances (EMA 2017; Brinker 2010; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000)

## 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.

|   |
|---|
| <b>Product Facts</b>  |
| <b>Medicinal ingredient</b> in each capsule<br>Willow bark ( <i>Salix alba</i> – bark) <span style="float: right;">XX mg</span>   |
| <b>Uses</b><br><ul style="list-style-type: none"> <li>• Used in Herbal Medicine for short-term relief of low back pain.</li> <li>• Used in Herbal Medicine to relieve minor joint pain due to osteoarthritis.</li> <li>• Used in Herbal Medicine to relieve fever associated with the common cold.</li> <li>• Used in Herbal Medicine to relieve headache.</li> </ul> |
| <b>Warnings</b>   |
| <b>If applicable<sup>1</sup>:</b><br><b>Allergens: food allergen, gluten (gluten source), sulphites</b><br><b>Contains aspartame</b>  |
| <b>Do not use if</b> • you are pregnant or breastfeeding • you are allergic to salicylates.   |
| <b>Ask a health care practitioner before use if</b> • you have asthma or peptic ulcer disease • you are taking blood thinners or products containing salicylates.   |
| <b>When using this product</b> you may experience gastrointestinal discomfort.  |
| <b>Ask a health care practitioner if</b> symptoms persist or worsen.  |
| <b>Directions</b><br>Adults 18 years and older: Take X capsule(s), X time(s) a day • Ask a health care practitioner for use beyond 6 weeks.   |
| <b>Other information</b><br>(Add storage information)   |
| <b>Non-medicinal ingredients</b><br>List all NMIs   |
| <b>Questions?</b> (Call) 1-XXX-XXX-XXXX   |

<sup>1</sup> This section can be removed from the table if the product contains no allergen or aspartame.

**References cited**

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Chrubasik S, Eisenberg E, Balan E, Weinberger T, Luzzati R, Conradt C. Treatment of low back pain exacerbations with willow bark extract: a randomised double-blind study. *The American Journal of Medicine*. 2000; 109: 9–14.

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