

## 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

October 28, 2022

#### 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>	Young branch bark	Dry

References: Proper name: Blumenthal et al. 2000, Bradley 1992; Common name: Blumenthal et al. 2000, Bradley 1992; Source information: USDA 2019, 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 low back pain (EMA 2017).
- ▶ (Traditionally) used in Herbal Medicine to relieve minor joint pain (due to osteoarthritis) (EMA 2017; ESCOP 2003).
- ▶ (Traditionally) used in Herbal Medicine to relieve fever associated with the common cold (EMA 2017).
- ▶ (Traditionally) used in Herbal Medicine to relieve headache pain (EMA 2017).

The following combined use(s) or purpose(s) is/are also acceptable:

(Traditionally) used in Herbal Medicine to relieve minor joint pain (due to osteoarthritis), headache pain and for short-term relief of low back pain (EMA 2017; ESCOP 2003).

## Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

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

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use (EMA 2017; Beer and Wegener 2008; Biegert et al. 2004; Chrubasik 2000).

## Risk information

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

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have asthma or peptic ulcer disease (EMA 2017).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking anticoagulants or products containing acetylsalicylic acid (ASA) or other salicylates (EMA 2017).

### Contraindication(s)

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

### Known adverse reaction(s)

Some people 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* (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.

## References cited

Barnes J, Anderson LA, Philipson JD. Herbal Medicines: A Guide for Healthcare Professionals. 2<sup>nd</sup> edition. London (GB): The Pharmaceutical Press; 2002.

Beer A.-M, Wegener T. Willow bark extract (*Salicis cortex*) for gonarthrosis and coxarthrosis- Results of a cohort study with a control group. Journal of Phytomedicine 2008; 15: 907-913.

Biegert C, Wagner I, Ludtke R, Kotter I, Lohmuller C, Gunaydin I, Taxis K, Heide L. Efficacy and safety of willow bark extract in the treatment of osteoarthritis and rheumatoid arthritis: results of 2 randomized double-blind controlled trials. Journal of Rheumatology 2004; 31 (11): 2121–2130.

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

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (GB): British Herbal Medicine Association; 1992.

Brinker F. Herb Contraindications and Drug Interactions, 3<sup>rd</sup> edition. Sandy (OR): Eclectic Medical Publications; 2010.

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.

EMA 2017. European Medicines Agency. European Union herbal monograph on *Salix* [various species including *S. purpurea* L., *S. daphnoides* Vill., *S. fragilis* L.], cortex. London (GB): EMA Committee on Herbal Medicinal Products (HMPC), 31 January 2017. [Accessed 2022 September 2]. Available at: [https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-salix-various-species-including-s-purpurea-l-s-daphnoides-vill\\_en.pdf](https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-salix-various-species-including-s-purpurea-l-s-daphnoides-vill_en.pdf)

ESCOP 2003: E/S/C/O/P Monographs: The Scientific Foundation for Herbal Medicinal Products. 2<sup>nd</sup> edition. Exeter (GB): ESCOP, the European Scientific Cooperative on Phytotherapy in collaboration with Georg Thieme Verlag and Thieme; 2003.



USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 July 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>

Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. 3<sup>rd</sup> edition. Stuttgart (DE): Medpharm Scientific Publishers; 2004.

WHO 2009: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva (CH): World Health Organization; 2009.