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
October 18, 2013

NHPID Name
Willow Bark

Proper name(s)
Willow Bark (Bradley 1992; Blumenthal et al. 2000)

Common name(s)
Willow Bark (Bradley 1992; Blumenthal et al. 2000)

Source material(s)
Salix alba L. - Young branch bark (USDA 2007; Wichtl 2004; ESCOP 2003; Blumenthal et al. 2000)
Salix daphnoides Vill. - Young branch bark (USDA 2007; Wichtl 2004; ESCOP 2003; Blumenthal et al. 2000)
Salix x fragilis L. - Young branch bark (USDA 2007; Wichtl 2004; ESCOP 2003; Blumenthal et al. 2000)
Salix purpurea L. - Young branch bark (USDA 2007; Wichtl 2004; ESCOP 2003; Blumenthal et al. 2000)
**Route(s) of administration**

Oral

**Dosage form(s)**

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s)**

- Used in Herbal Medicine for short-term relief of low back pain (EMEA 2009).
- (Traditionally) used in Herbal Medicine for the relief of minor joint pain (due to osteoarthritis) (EMEA 2009; ESCOP 2003).
- (Traditionally) used in Herbal Medicine to relieve fever associated with the common cold (EMEA 2009).
- (Traditionally) used in Herbal Medicine to relieve headache pain (EMEA 2009).

**Note**

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

**Dose(s)**

**Subpopulation(s)**

Adults (≥ 18 years)

**Quantity(ies)**

*Dry, Powder, Decoction & Infusion + All Non-Standardized Extracts*

3-9 g dried bark per day in divided doses, not to exceed 3 g per dose (EMEA 2009; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000)

*Standardized Extracts*

45 to 240 mg total salicin per day in divided doses, not to exceed 120 mg salicin per dose (EMEA 2009; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000) or 0.5-1% total salicin (after hydrolysis) (WHO 2009)
**Duration of use**

Statement(s) to the effect of

For prolonged use, consult a health care practitioner (EMEA 2009; Beer and Wegener 2008; Biegert et al. 2004; Chrubasik 2000).

**Risk information**

Statement(s) to the effect of

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

- If symptoms persist or worsen, consult a health care practitioner.
- If you experience gastrointestinal symptoms such as nausea, vomiting, abdominal pain, dyspepsia, heartburn or diarrhea, discontinue use and consult a health care practitioner (Brinker 2010; EMEA 2009; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000).
- If you have asthma or peptic ulcer disease, consult a health care practitioner prior to use (EMEA 2009).
- If you are taking anticoagulants or products containing acetylsalicylic acid (ASA) or other salicylates, consult a health care practitioner prior to use (EMEA 2009).

**Contraindication(s)**

- If you are allergic to acetylsalicylic acid (ASA) or other salicylates, do not use this product (Brinker 2010; EMEA 2009; Wichtl 2004, ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000).
- If you are pregnant or breastfeeding, do not use this product (Brinker 2010; EMEA 2009; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Blumenthal et al. 2000).

**Known adverse reaction(s)**

No statement required.

**Non-medicinal ingredients**

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* (NHPID) and must meet the limitations outlined in the database.

**Storage conditions**

Statement(s) to the effect of

No statement required.

**Specifications**
The finished product specifications must be established in accordance with the requirements described in the NHPD Quality of Natural Health Products Guide.

The medicinal ingredient must comply with the requirements outlined in the Natural Health Products Ingredients Database (NHPID).

References cited


