Health Canada Santé Canada

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 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) Statement(s) to the effect of

- 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) Statement(s) to the effect of

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

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