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 February 8, 2013

Proper name(s)


Common name(s)

- Ceylon cinnamon (Merck 2012; BHC 2006; Blumenthal et al. 2000; McGuffin et al. 2000)
- True cinnamon (Blumenthal et al. 2000; McGuffin et al. 2000)

Source material(s)

- Branch bark (Blumenthal et al. 2000, 1998)

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 to the effect of

- Provides antioxidants (Gruenwald et al. 2010; Roussel et al. 2009; Halvorsen et al. 2006; Shan et al. 2005).

- (Traditionally) used in Ayurveda for bowel complaints such as dyspepsia, flatulency, diarrhea and vomiting (Paranjpe 2005[2001]; Kapoor 2001).

- (Traditionally) used in Herbal Medicine for digestive disturbances/digestive complaints such as mild spasms/cramps of the gastrointestinal tract/gastrointestinal colic, feeling of repletion/bloating, and flatulence/carinative (Godfrey et al. 2010; BHC 2006; Wichtl 2004; Blumenthal et al. 2000, 1998).

- (Traditionally) used in Herbal Medicine for loss of appetite (BHC 2006; Wichtl 2004; Blumenthal et al. 2000, 1998).

Note
A claim for a traditional use must include either the term “Herbal Medicine” or “Ayurveda”.

Dose(s) Statement to the effect of

Subpopulation(s)

adults (≥ 19 years)

Quantity(ies)

FLUIDEXTRACT

Non-Ayurveda products, excluding antioxidants:
1:1 (g/ml) in 70% alcohol
0.5-1.3 ml (BHC 2006; Blumenthal et al. 2000).
INFUSION AND DECOCTION

Antioxidant:
Up to 1.5 g cut or ground bark, per day. Prepare with 150 ml of water (API 2001[1990]; Kapoor 2001).

Non-Ayurveda products excluding antioxidant:
0.7-1.5 g cut or ground bark, per day. Prepare with 150 ml of water (BHC 2006; Wichtl 2004; Blumenthal et al. 2000, 1998).

POWDER

Antioxidant:
Up to 4 mg bark powder, per day (API 2001[1990]; Kapoor 2001).

Ayurveda products:
1-3 g bark powder, per day (API 2001[1990]; Kapoor 2001)

For non-Ayurveda products, excluding antioxidants:
2-4 g bark powder, per day (BHC 2006; Wichtl 2004; Blumenthal et al. 2000, 1998).

TINCTURE

Non-Ayurveda products, excluding antioxidants:
1:5 (g/ml) in 70% alcohol (Ph.Eur. 2012; BHC 2006)
2-6.7 ml (BHC 2006; Blumenthal et al. 2000).

Directions for use

All products, excluding antioxidants:
Take three times daily.

Loss of appetite:
Take a half hour before meals.

Digestive discomfort:
Take after food/meal (Wichtl 2004).

Note
Refer to Appendix 1 for examples of dosage preparations and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use

No statement required.
Risk information

Statement to the effect of Caution(s) and warning(s)

All products:
- If you are breastfeeding, consult a health care practitioner prior to use (Blumenthal et al. 2000; WHO 1999).
- If you have diabetes, consult a health care practitioner prior to use (NS 2012; Brinker 2010)

Loss of appetite or digestive discomforts:
If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

If you are pregnant, do not use this product (Brinker 2010; BHC 2006; Blumenthal 2000, 1998).

Known adverse reaction(s)

No statement required.

Storage conditions

No statement required.

Non-medicinal ingredients

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

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). In addition, the medicinal ingredient may comply with the quality specifications outlined in the current Cinnamon - Cinnamomi cortex or the Cinnamon tincture - Cinnamomi corticis tinctura monographs in the European Pharmacopoeia.

References cited


Brinker 2010: Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13 2010; Accessed 2012 June 1]. Available from: http://www.eclecticherb.com/emp/uploadsHCDI.html


**References reviewed**


Appendix 1  Examples of dosage preparations and directions for use

Godfrey et al. 2010
Powdered bark: 5-20 gr. (~0.3-1.2 g)
Tincture: 2-4 ml tid

BHC 2006
Three times daily:
Dried bark: 0.5-1 g as an infusion
Liquidextract: 1:1 in 70% alcohol, 0.5-1 ml
Tincture: BPC 1949, 1:5 in 70% ethanol, 2-4 ml

Wichtl 2004
2-4 g dried bark

API 2001[1990]
1-3 g powdered bark, per day

Kapoor 2001
0.5-1.5 g bark

Blumenthal 2000
2-4 g per day of cut or ground bark
Infusion or decoction: 0.7-1.3 g in 150 ml of water, three times daily
Fluidextract: 1:1 (g/ml), 0.7-1.3 ml, three times daily
Tincture: 1:5 (g/ml): 3.3-6.7 ml, three times daily

Blumental 1998
2-4 g bark