NATURAL HEALTH PRODUCT

BLACK PEPPER – *Piper nigrum*

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

June 11, 2014

Proper name(s)

*Piper nigrum* L. (Piperaceae) (Duke 2009; USDA 1995)

Common name(s)

- Black pepper (USDA 1995)
- White pepper (USDA 1995)

Source material(s)

Fruit (CNF 2009)

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

*Powdered *Piper nigrum*

- Traditionally used in Ayurvedic medicine to improve digestion (API 2001).
- Traditionally used in Ayurvedic medicine as an antiparasitic (API 2001).

Dose(s)

Subpopulation(s)

Adults (≥ 18 years)

Quantity

*Powdered Piper nigrum*

250-420 mg dried fruit, per day (CNF 2012; API 2001).

*Piperine (valid only for Class II and III applications)*

Up to 14 mg piperine per day as a pure isolate or as a constituent of standardized *Piper nigrum* fruit extracts (TGA 2007).

Duration of use Statement(s) to the effect of

*All Products*

For use beyond 12 weeks, consult a health care practitioner (Lieberman et al. 2005).

*Antiparasitic*

For occasional use only.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

*All products*

- If you are pregnant or breastfeeding, consult a healthcare practitioner prior to use.
If you are taking any other medications or natural health products, consult a health care practitioner prior to use, as black pepper/piperine may alter their effectiveness (Han 2011; Srinivasan 2007; Khajuria et al. 2002; Bano et al. 1991).

**Antiparasitic**

If symptoms worsen of if they persist for more than 2 weeks, consult a health care practitioner.

**Contraindication(s)**

No statement required.

**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**

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**


Han HK. The effects of black pepper on the intestinal absorption and hepatic metabolism of drugs. Expert Opinion on Drug Metabolism & Toxicology 2011;7(6):721-729.


References reviewed