

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 or 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).

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Duke 2009: Dr. Duke's Phytochemical and Ethnobotanical Databases. Phytochemical databases [Internet]. [Accessed 2009 November 19] Available at <http://www.ars-grin.gov/duke/plants.html>.