

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 statements are synonymous. Either term or statement may be selected by the applicant.

Date

December 24, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Piper nigrum</i>	<ul style="list-style-type: none"> ▶ Black pepper ▶ White pepper ▶ Pepper-black ▶ Pepper-white 	<i>Piper nigrum</i>	Fruit	Dried
1-[(2E,4E)-5-(1,3-Benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]piperidine	Piperine	<i>Piper nigrum</i>	Fruit	N/A

References: Proper names: USDA 2018, O'Neil et al. 2013, Duke 2009; Common names: USDA 2018, O'Neil et al. 2013; Source materials: CNF 2018.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Powdered Piper nigrum fruit (unextracted)

- ▶ Traditionally used in Ayurveda to improve digestion (API 2001).
- ▶ Traditionally used in Ayurveda as an antiparasitic (API 2001).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Piperine isolated from the fruit

No claim (safety only)

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Ayurvedic claims

Method of preparation: Powdered (unextracted)

250-420 milligrams of dried fruit, per day (CNF 2018; API 2001).

Piperine as an isolate from the fruit - No claim (safety only)

Method of preparation: Isolate

Not to exceed 14 milligrams of piperine, per day (TGA 2007).

Direction(s) for use

No statement required.



Duration(s) of use

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 12 weeks (Lieberman et al. 2005).

Antiparasitic

For occasional use only.

Risk information

Caution(s) and warning(s)

All products

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

Antiparasitic

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if they persist for more than 2 weeks.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current 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 Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited

API 2001: The Ayurvedic Pharmacopeia of India-part I, Ministry of Health and Family Welfare, Government of India, New Delhi (IN): The Controller of Publications; 2001.

Bano G, Raina RK, Zutshi U, Bedi KL, Johri RK, Sharma SC. Effect of piperine on bioavailability and pharmacokinetics of propranolol and theophylline in healthy volunteers. *European Journal of Pharmacology* 1991;41(6):615-7.

CNF 2018: Canadian Nutrient File, Food and Nutrition, Health Canada [Internet]. [Accessed 2018 August 14] Available from: <https://food-nutrition.canada.ca/cnf-fce/index-eng.jsp>

Duke 2009: Dr. Duke's Phytochemical and Ethnobotanical Databases. Phytochemical databases [Internet]. [Accessed 2018 August 14] Available from: <http://www.ars-grin.gov/duke/plants.html>.

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.

Khajuria A, Thusu N, Zutshi U. Piperine modulates permeability characteristics of intestine by inducing alterations in membrane dynamics: influence on brush border membrane fluidity, ultrastructure and enzyme kinetics. *Phytomedicine* 2002;9(3):224-31.

Lieberman S, Spahrs R, Stanton A, Martinez L, Grinder M. 2005. Weight loss, body measurements, and compliance: A 12-week total lifestyle intervention pilot study. *Alternative & Complementary Therapies* 2005(December):307-313.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals*. 15th edition. Whitehouse Station (NJ): Merck & Co., Inc; 2013.

Srinivasan K. Black Pepper and its pungent principle-piperine: a review of diverse physiological effects. *Critical Reviews in Food Science and Nutrition* 2007;47(8):735-748.



TGA 2007: Australian Therapeutic Goods Administration. CMEC 64: Complementary Medicines Evaluation Committee, Extracted Ratified Minutes Sixty-fourth Meeting, 14 December 2007. Australian Government Department of Health and Aging, Sydney, Australia;2007. [Accessed 2018 August 14]. Available from: <https://www.tga.gov.au/sites/default/files/cmec-minutes-64.pdf>

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. *Piper nigrum* L. National Germplasm Resources Laboratory, Beltsville (MD). [Last updated 1995 May 26; Accessed 2018 August 14]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

References reviewed

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