

# Black Pepper - Piper nigrum

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BLACK PEPPER - PIPER NIGRUM Help on accessing alternative formats, such as Portable Document Format ( PDF ), Microsoft Word and PowerPoint ( PPT ) files, can be obtained in the alternate format help section. (PDF Version - 51 KB) 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 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 on the label. Date November 29, 2024 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Piper nigrum Black pepper White pepper Pepper-black Pepper-white Piper nigrum Fruit Dried 1-[(2E,4E)-5-(1,3-Benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]piperidine Piperine Piper nigrum Fruit N/A References: Proper names: RSC 2024; USDA 2024; Duke 2009; Common names: RSC 2024; USDA 2024; Source information: CNF 2023. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Application form for Compendial applications. Use(s) or Purpose(s) Powdered Piper nigrum (unextracted) Traditionally used in Ayurveda to improve digestion (API 2001). Traditionally used in Ayurveda as a vermifuge/anthelmintic (API 2001). Notes For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Black pepper is traditionally used in Ayurveda to improve digestion). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Piperine isolated from the fruit No claim (safety only) Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Ayurvedic claims 250-420 milligrams of dried fruit, per day (CNF 2023; API 2001). \*Note: The method of preparation 'powder' is defined as a dried and ground preparation (= unextracted). Piperine as an isolate from the fruit - No claim (safety only) Not to exceed 14 milligrams of piperine, per day (TGA 2007). Direction(s) for use No statement required. Combination rules Combination of black pepper and piperine within this monograph (Class I) is not permitted as this monograph only includes Ayurvedic medicine claims and the isolation of the constituent piperine is not a traditional method of preparation used in Ayurvedic medicine. Combination of black pepper and piperine outside this monograph for safety only is allowed if the total amount of piperine does not exceed 14 mg per day. Duration(s) of Use Improve digestion Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 12 weeks (Lieberman et al. 2005). Vermifuge/anthelmintic For occasional use only. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking medications or any other health products, as black pepper/piperine may alter their effectiveness (Han 2011; Srinivasan 2007; Khajuria et al. 2002; Bano et al. 1991). Improve digestion Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Vermifuge/anthelmintic Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations. 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. EXAMPLE

OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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 2023: Canadian Nutrient File, Food and Nutrition, Health Canada. [Accessed 2024 March 4] Available from: <https://food-nutrition.canada.ca/cnf-fce/?lang=eng> Duke 2009: Dr. Duke's Phytochemical and Ethnobotanical Databases. Phytochemical databases. [Accessed 2024 March 24] Available from: <https://phytochem.nal.usda.gov/> 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. RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 March 4]. Available from: <https://merckindex.rsc.org/> 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 2024 March 4]. Available from: <https://www.tga.gov.au/sites/default/files/cmec-minutes-64.pdf> USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 March 4]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> 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>. Report a problem on this page Date modified: 2019-03-01

## **DOSAGE FORM(S)**

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Application form for Compendial applications.

## **RISK INFORMATION**

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking medications or any other health products, as black pepper/piperine may alter their effectiveness (Han 2011; Srinivasan 2007; Khajuria et al. 2002; Bano et al. 1991). Improve digestion Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Vermifuge/anthelmintic Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Piper nigrum	Black pepperWhite pepperPepper-blackPepper-white	Piper nigrum	Fruit	Dried
1-[(2E,4E)-5-(1,3-Benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]piperidine	Piperidine	Piper nigrum	Fruit	N/A