

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 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)
<i>Piper nigrum</i>	<ul style="list-style-type: none"> • Black pepper • White pepper • Pepper-black • Pepper-white 	<i>Piper nigrum</i>	Fruit	Dry
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: 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 fruit (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

Method of preparation: Powdered*

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.

Product Facts	
Medicinal ingredient in each capsule <i>Piper nigrum</i> (Black pepper – fruit) mg	XX
Uses Traditionally used in Ayurveda to improve digestion.	
Warnings	
If applicable¹:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Ask a health care practitioner before use if • you are pregnant or breastfeeding • you are taking any other medications or health products, as black pepper may alter their effectiveness.	
Ask a health care practitioner if symptoms persist or worsen.	
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Ask a health care practitioner for use beyond 12 weeks.	
Other information (Add storage information).	
Non-medicinal ingredients List all NMIs.	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame.

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.

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Duke 2009: Dr. Duke's Phytoschemical and Ethnobotanical Databases. Phytochemical databases. [Accessed 2024 March 24] Available from: <https://phytochem.nal.usda.gov/>

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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.

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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>