

NATURAL HEALTH PRODUCT

BLACK HOREHOUND – *BALLOTA NIGRA*

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

January 31, 2025

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>Ballota nigra</i>	<ul style="list-style-type: none"> • Ballotta • Black hempnettle • Black horehound • Black stinking horehound • Marrubium nigrum 	<i>Ballota nigra</i>	Herb top	Dry

References: Proper name: USDA 2024; Common names: Barnes et al. 2007; Gardner and McGuffin 2013; Grieve 1971; Source information: BHP 1983.

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 Licence Application form for Compendial applications.

Use(s) or Purpose(s)

- (Traditionally) used in Herbal Medicine (as an antiemetic) to help relieve nausea and vomiting (Bradley 2006; Hoffmann 2003; Williamson et al. 1988).
- (Traditionally) used in Herbal Medicine (as an antispasmodic) to help relieve digestive spasms (Bradley 2006; Williamson et al. 1988; Felter and Lloyd 1983; Grieve 1971).

Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help relieve digestive spasms, nausea and vomiting).
- **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 the traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Black horehound is traditionally used in Herbal Medicine to help relieve nausea and vomiting).
 - 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.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

0.3 – 12 grams of dried herb tops, per day (Bradley 2006; Hoffmann 2003; BHP 1983).

***Note:** Solvents allowed for the method of preparation “Non-standardized extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding.**

Contraindication(s)

Do not use if you are pregnant (Brinker 2010).

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>Ballota nigra</i> (Black horehound) X:1 extract Equivalent to YY g of dried herb top	XX mg
Uses <ul style="list-style-type: none"> • Traditionally used in Herbal Medicine to help relieve nausea and vomiting. • Traditionally used in Herbal Medicine to help relieve digestive spasms. 	
Warnings	
If applicable¹:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Do not use if you are pregnant.	
Ask a health care practitioner before use if you are breastfeeding.	
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.	
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

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BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety

Handbook. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013.

Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003.

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 February 13]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988.