

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 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

August 28, 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>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	Dried

References: Proper name: USDA 2018; Common names: Barnes et al. 2007; McGuffin et al. 2000; Grieve 1971; Source material: 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 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)

- ▶ Traditionally used in Herbal Medicine to help relieve nausea and vomiting (anti-emetic) (Bradley 2006; Hoffmann 2003; Williamson et al. 1988).
- ▶ Traditionally used in Herbal Medicine to help relieve digestive spasms (anti-spasmodic) (Bradley 2006; Williamson et al. 1988; Felter and Lloyd 1983; Grieve 1971).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Herbal Medicine to help relieve digestive spasms (anti-spasmodic) and/or nausea and vomiting (anti-emetic) (Bradley 2006; Hoffmann 2003; Williamson et al. 1988; Felter and Lloyd 1983; Grieve 1971).

Note

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

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

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

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.



- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are breastfeeding.

Contraindication(s)

Do not use this product 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

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

Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3rd edition. London (UK): The Pharmaceutical Press; 2007.

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].

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.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Ballota nigra* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 June 15]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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

References reviewed

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997.