EUROPEAN PENNYROYAL

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

Date
February 29, 2012

Proper name(s)
*Mentha pulegium* L. (Lamiaceae) (USDA 2011)

Common name(s)
European pennyroyal (McGuffin et al. 2000)

Source material(s)
Aerial parts (BHP 1983)

Route(s) of administration
Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)
Statement(s) to the effect of:

- (Traditionally) used in Herbal Medicine to aid digestion (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983; Grieve 1971 [1931]).
(Traditionally) used in Herbal Medicine to help relieve flatulent dyspepsia (carminative) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983).

(Traditionally) used in Herbal Medicine to help relieve intestinal colic (anti-spasmodic) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983; Grieve 1971 [1931]).

**Dose(s)**

**Powder:**
3-12 g dried aerial parts, per day (BHP 1983; Grieve 1971 [1931])

**Infusion:**
3-12 g dried aerial parts, per day (BHP 1983; Grieve 1971 [1931])

**Fluidextract:**
3-12 g dried aerial parts, per day
(1:1, 45% alcohol, 3-12 ml) (Mills and Bone 2005; Williamson et al. 1988; BHP 1983)

**Directions for use for the above dosages:**
Take 3-4 g, up to 3 times per day (Mills and Bone 2005; BHP 1983)

**Tincture:**
600-1200 mg dried aerial parts, per day

**Directions for use for tincture:**
Take in one dose or in two to three divided doses (Mills and Bone 2005; Hoffman 2003).

Refer to Appendix 1 for examples of appropriate dosage preparations and frequencies of use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use**
No statement required.

**Risk information**
Statement(s) to the effect of:

**Caution(s) and warning(s):**

› Consult a health care practitioner if symptoms persist or worsen.
› Consult a health care practitioner prior to use if you have liver or kidney problems (Brinker 2000; McGuffin 1997).
› Consult a health care practitioner prior to use if you are taking acetaminophen (Brinker 2000).
Contraindication(s): Do not use if you are pregnant or breastfeeding (Brinker 2010).

Known adverse reaction(s): No statement required.

Non-medicinal ingredients
Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications
The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.

References cited


References reviewed


Brinker F. Herb Contraindications and Drug Interactions, 3rd edition, including extensive appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. Sandy (OR): Eclectic Medical Publications; 2001.


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


Appendix 1: Examples of appropriate dosage preparations and frequencies of use

Dried aerial parts: 1-4 g, 3 times per day (BHP 1983)

Infusion: 1-4 g dried aerial parts, 3 times per day (BHP 1983)

Fluidextract:
  ▶ 1-4 g dried equivalent, 3 times per day
      (1:1, 45% alcohol, 1-4 ml) (BHP 1983)
  ▶ 2-4 g dried equivalent, per day
      (1:1, 1-4 ml) (Grieve 1971 [1931])

Tincture:
  ▶ 1 to 2 ml three times a day (1:5 in 40%) (Hoffman 2003)
  ▶ 3-6 ml/d of a 1:5 tincture (Mills and Bone 2005)