



NATURAL HEALTH PRODUCT

PEPPERMINT – *MENTHA X PIPERITA*

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: July 18, 2017

Proper name(s):

Mentha x piperita L. (Lamiaceae) (USDA 2006)

Common name(s):

Peppermint (McGuffin et al. 2000)

Essential oil :
Peppermint essential oil

Source material(s):

Leaf (ESCOP 2003)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:

- **Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

Use(s) or Purpose(s):

All source materials:

- ▶ Traditionally used in Herbal Medicine to aid digestion (stomachic) (Boon and Smith 2004; Blumenthal et al. 2000; Felter and Lloyd 1983 [1898]).
- ▶ Traditionally used in Herbal Medicine to help relieve flatulent dyspepsia (carminative) (ESCOP 2003; Hoffmann 2003; Bradley 1992; Felter and Lloyd 1983 [1898]).

Essential oil:

Traditionally used in Herbal Medicine to help relieve nausea and vomiting (Boon and Smith 2004; Hoffmann 2003; Blumenthal et al. 2000; Felter and Lloyd 1983 [1898]).

Dose(s):

Table 1: Dose information for peppermint leaf presented as dose per day

Subpopulation		Peppermint leaf (g/day)	
		Minimum	Maximum
Children ¹	2-4 y	0.2	2
Children and adolescents ¹	5-9 y	0.3	3
Adolescents ¹	10-14 y	0.6	6
Adolescents and adults ^{1,2}	≥ 15 y	1.2	12

¹ Children and adolescent doses were calculated as a fraction of the adult dose (JC 2008). The use of peppermint leaf in children and adolescents is supported by the following references: McIntyre 2005; Bove 1996.

² Adult dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; Bradley 1992

Table 2: Dose information for peppermint essential oil presented as dose per day

Subpopulation		Peppermint essential oil (µl/day)	
		Minimum	Maximum
Children ¹	2-4 y	10	130
Children and adolescents ¹	5-9 y	15	200



Subpopulation		Peppermint essential oil (µl/day)	
		Minimum	Maximum
Adolescents ¹	10-14 y	30	400
Adolescents and adults ^{1,2}	≥ 15 y	60	800

¹ Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of peppermint essential oil in children and adolescents is supported by the following references: McIntyre 2005; Bove 1996.

² Adult dose supported by the following references: ESCOP 2003; Blumenthal et al. 2000

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

Duration of use:

No statement required.

Risk information:

Caution(s) and warning(s):

All source materials:

- ▶ Consult a health care practitioner if symptoms persist or worsen.
- ▶ Consult a health care practitioner prior to use if you have gallstones (Brinker 2001; Blumenthal et al. 2000).
- ▶ Consult a health care practitioner prior to use if you have anaemia (Brinker 2007; Mills and Bone 2005).
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding (Brinker 2007; Mills and Bone 2005).

Essential oil:

Consult a health care practitioner prior to use if you have hiatus hernia or gastroesophageal reflux (Mills and Bone 2005; ESCOP 2003; Brinker 2001).

Contraindication(s):

No statement required.

Known adverse reaction(s):

Essential oil:

- ▶ Some people may experience gastroesophageal reflux (Mills and Bone 2005; ESCOP 2003; Brinker 2001).
- ▶ Hypersensitivity (e.g. allergy) has been known to occur; in which case, discontinue use (Mills and Bone 2005; ESCOP 2003).

Non-medicinal ingredients:

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

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.
- ▶ The medicinal ingredient may comply with the specifications outlined in the Peppermint, Peppermint Oil, Peppermint Spirit, or Peppermint Water Monographs published in the US Pharmacopoeia or the Peppermint Leaf or Peppermint Oil Monographs published in the European or British Pharmacopoeias.

References cited:

Blumenthal M, Goldberg A, Brinkmann J, editors. *Herbal Medicine: Expanded Commission E Monographs*. Boston (MA): Integrative Medicine Communications; 2000.

Boon H, Smith MJ. *The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs*, 2nd edition. Toronto (ON): Robert Rose Inc; 2004.

Bove M. *An Encyclopedia of Natural Healing for Children and Infants*. New Canaan (CT): Keats Publishing, Incorporated; 1996.

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Brinker F. *Herb Contraindications and Drug Interactions*, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

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

Giacoa GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

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

JC 2008: Justice Canada. *Food and Drug Regulations*. (C.01.021). Ottawa (ON): Justice Canada; 2008. [Accessed 2008-01-31] Available from: <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/text.html>

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

McIntyre A. *Herbal Treatment of Children - Western and Ayurvedic Perspectives*. Toronto (ON): Elsevier Limited; 2005.

Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

USDA 2006: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Mentha piperita* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2008-02-19]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl



Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

Leaf:

Dried leaf:

- ▶ 6-12 g, per day (Mills and Bone 2005)
- ▶ 3-6 g, per day (Blumenthal et al. 2000)
- ▶ 2-3 g, 3 times per day (Bradley 1992)

Infusion:

- ▶ 6-12 g dried leaf, per day (Mills and Bone 2005)
- ▶ 1.5-3 g dried leaf, 3 times per day (ESCOP 2003)
- ▶ 2 g dried leaf, 2 to 3 times per day (Blumenthal et al. 2000)
- ▶ 2-3 g dried leaf, 3 times per day (Bradley 1992)

Directions for use:

- ▶ Pour 250 ml of boiling water over dried leaf and infuse in a covered container for 10 minutes. This may be drunk as often as desired (Hoffmann 2003).
- ▶ Take on an empty stomach (Boon and Smith 2004).

Fluidextract:

2 g dried equivalent, 2 to 3 times per day
(1:1, 2 ml) (Blumenthal et al. 2000)

Tincture:

- ▶ 2 g dried equivalent, 2 to 3 times per day
(1:5, 10 ml) (Blumenthal et al. 2000)
- ▶ 0.4-0.6 g dried equivalent, 3 times per day
(1:5, in 45% ethanol, 2-3 ml) (Bradley 1992)

Directions for use: Take on an empty stomach (Boon and Smith 2004).

Solid extract:

1.54-2.57 g dried equivalent, 2 to 3 times per day
(3.5-4.5:1, 0.44-0.57 g) (Blumenthal et al. 2000)

Essential oil:

- ▶ 20-80 µl (1-4 drops), 3 times per day (ESCOP 2003)
- ▶ 400-800 µl (6-12 drops), per day (Blumenthal et al. 2000)

Directions for use: Take drops in water or on a lump of sugar (ESCOP 2003).