

Home > Drugs & Health Products > Natural Health Products Ingredients Database

Drugs and Health Products

PEPPERMINT - MENTHA X PIPERITA

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 (PDF Version - 78 KB)

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 information

Peppermint dried leaf

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>Mentha x piperita</i>	Peppermint	<i>Mentha x piperita</i>	Leaf	Dry

References: Proper name: USDA 2018; Common name: McGuffin et al. 2000; Source information: ESCOP 2003.

Peppermint essential oil

Table 2. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<i>Mentha x piperita</i>	Peppermint essential oil	<i>Mentha x piperita</i>	Leaf

References: Proper name: USDA 2018; Source information: ESCOP 2003.

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 Compdial applications.

Use(s) or Purpose(s)

All products

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

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

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

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).

Note

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

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

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

Table 3. Dose information for peppermint dried leaf presented as dose (grams) per day

Subpopulation(s) ^{1,2}		Peppermint dried leaf (g/day)	
		Minimum	Maximum
Children	2-4 years	0.2	2
	5-9 years	0.3	3
	10-11 years	0.6	6
Adolescents	12-14 years	0.6	6
	15-17 years	1.2	12
Adults	18 years and older	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.

Method of preparation: Oil, Essential (water steam distillation)

Table 4. Dose information for peppermint essential oil presented as dose (microliters) per day

Subpopulation(s) ^{1,2}		Peppermint essential oil (µl/day)	
		Minimum	Maximum
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.			

		Minimum	Maximum
Children	2-4 years	10	130
	5-9 years	15	200
	10-11 years	30	400
Adolescents	12-14 years	30	400
	15-17 years	60	800
Adults	18 years and older	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.

Direction(s) for use

No statement required.

Combination rule

No permitted combinations. This monograph only supports single ingredient products.

Duration(s) of Use

No statement required.

Risk Information

Caution(s) and warning(s)

All products

- 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 pregnant or breastfeeding, or have gallstones or anaemia (Brinker 2010; Mills and Bone 2005; Blumenthal et al. 2000).

Essential oil

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use prior to use if you have hiatus hernia or gastroesophageal reflux (Brinker 2010; Mills and Bone 2005; ESCOP 2003).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Essential oil

- Some people may experience gastroesophageal reflux (Brinker 2010; Mills and Bone 2005; ESCOP 2003).
- Stop use if hypersensitivity/allergy occurs (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.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations* (NHPR).

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

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