

NATURAL HEALTH PRODUCT

PSYLLIUM – *PLANTAGO ARENARIA*

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 labels 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

October 30, 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>Plantago arenaria</i>	<ul style="list-style-type: none"> ▶ French psyllium ▶ Psyllium ▶ Sand plantain 	<i>Plantago arenaria</i>	<ul style="list-style-type: none"> ▶ Seed ▶ Husk 	Dried

References: Proper name: USDA 2018; Common names: EMEA 2013a, ESCOP 2003a, McGuffin et al. 2000; Source materials: EMEA 2013a, USP 32 2009, ESCOP 2003a.

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)

- ▶ (Used in Herbal Medicine as a) bulk-forming laxative (ESCOP 2003a; ESCOP 2003b; ESCOP 20003c; Williamson 2003; FDA 1985).
- ▶ (Used in Herbal Medicine to) promote(s) bowel movements (by increasing bulk volume and water content) (Sweetman 2007; WHO 2007; ESCOP 2003a; ESCOP 2003b; ESCOP 20003c; Bradley 1992; FDA 1985).
- ▶ (Used in Herbal Medicine to) provide(s) gentle relief of constipation and/or irregularity (EMA 2013a; EMA 2013b; EMA 2013c; Pray 2006; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Blumenthal et al. 2000; Gennaro 2000; Bradley 1992; FDA 1985).

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

(Used in Herbal Medicine as a) bulk-forming laxative to provide gentle relief of constipation and/or irregularity and promote bowel movements (by increasing bulk volume and water content) (EMA 2013a; EMA 2013b; EMA 2013c; Sweetman 2007; WHO 2007; Pray 2006; ESCOP 2003a; ESCOP 2003b; ESCOP 20003c; Blumenthal et al. 2000; Gennaro 2000; Bradley 1992; FDA 1985).

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Dry, Powder

Table 2. Dose information for psyllium seed

Subpopulation(s)		Seed (grams)		
		Minimum/day	Maximum/day	Maximum/single dose ³
Children ¹	6-11 years	1.25 g	25 g	8 g
Adolescents ²	12 years	1.25 g	25 g	8 g
	13-17 years	2.5 g	40 g	13 g
Adults ²	18 years and older	2.5 g	40 g	13 g

¹EMA 2013a; EMA 2013b; ESCOP 2003a; ESCOP 2003b; WHO 1999; FDA 1985

²EMA 2013a; EMA 2013b; ESCOP 2003a; ESCOP 2003b; Williamson 2003; Blumenthal et al. 2000a; Blumenthal et al. 2000b; WHO 1999; FDA 1985

³ Note: The maximum single dose (13 g) for adults and adolescents 13 years and older is based on the consensus of evidence from several references. The maximum single dose (8 g) for children and adolescents up to 12 years was calculated as a fraction of the maximum adult doses

Table 3. Dose information for psyllium husk

Subpopulation(s)		Husk (grams)		
		Minimum/day	Maximum/day	Maximum/single dose ³
Children ¹	6-11 years	1.25 g	15 g	4 g
Adolescents ²	12 years	1.25 g	15 g	4 g
	13-17 years	2.5 g	30 g	8 g
Adults ²	18 years and older	2.5 g	30 g	8 g

¹EMEA 2013c; ESCOP 2003c; FDA 1985

²EMEA 2013c; ESCOP 2003c; Williamson 2003; Blumenthal et al. 2000c; Bradley 1992; FDA 1985

³ Note: The maximum single dose (8 g) for adults and adolescents 13 years and older is based on the consensus of evidence from several references. The maximum single dose (4 g) for children and adolescents up to 12 years was calculated as a fraction of the maximum adult doses.

Direction(s) for use

- ▶ For each gram of psyllium, mix with 30 ml of liquid (water, milk, fruit juice or similar aqueous beverage). Stir briskly and drink immediately. Maintain adequate fluid intake (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Blumenthal et al. 2000a; Blumenthal et al. 2000b; Blumenthal et al. 2000c; WHO 1999).
- ▶ Take a few hours before or after taking other medications or natural health products (EMEA 2013a; EMEA 2013b; EMEA 2013c; Sweetman 2007; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Blumenthal et al. 2000b; Blumenthal et al. 2000c; Bradley 1992).
- ▶ Effects observed 12-24 hours after first dose, and may take 2-3 days (EMEA 2013a; EMEA 2013b; EMEA 2013c).

For all products (Optional)

Take during the day (not immediately prior to bedtime) (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c).

For products with a dosage range (Optional)

Minimum daily dose may be increased, up to the maximum daily dose, until desired effect is obtained.



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 worsen or if laxative effect does not occur within 7 days (Pray 2006; Repchinsky 2002).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician immediately if you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have symptoms such as abdominal pain, nausea, vomiting or fever (as these could be signs of other serious conditions) (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Blumenthal et al. 2000a; Blumenthal et al. 2000b; Blumenthal et al. 2000c; Bradley 1992; FDA 1985).

Contraindication(s)

- ▶ Do not use this product if you have difficulty swallowing (EMEA 2013a; EMEA 2013b; EMEA 2013c).
- ▶ Do not use this product if you have diabetes mellitus in which blood sugar is difficult to regulate (EMEA 2013a; EMEA 2013b; EMEA 2013c; Blumenthal et al. 2000a; Blumenthal et al. 2000b; Blumenthal et al. 2000c; Bradley 1992).
- ▶ Do not use this product if you are experiencing a sudden change in bowel habits that has persisted for more than 2 weeks, undiagnosed rectal bleeding, or failure to defaecate following the use of another laxative product (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c).

Known adverse reaction(s)

- ▶ Stop use if hypersensitivity/allergy occurs (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Blumenthal et al. 2000a; Blumenthal et al. 2000b; Blumenthal et al. 2000c; Bradley 1992).
- ▶ May cause temporary gas and/or bloating (EMEA 2013a; EMEA 2013b; EMEA 2013c; ESCOP 2003a; ESCOP 2003b; ESCOP 2003c; Bradley 1992).



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.

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