

NATURAL HEALTH PRODUCT

AMLA – *PHYLLANTHUS EMBLICA*

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

December 18, 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>Phyllanthus emblica</i>	<ul style="list-style-type: none"> ▶ Amalaki ▶ Amla ▶ Emblic ▶ Emblic myrobalan ▶ Indian-gooseberry ▶ Myrobalan 	<i>Phyllanthus emblica</i>	Fruit	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: ITIS 2018, USDA 2018, Martindale 2011, API 2001, McGuffin et al. 2000; Source material: API 2001, Khory and Katrak 1999.

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)

- ▶ Source of/Provides antioxidants (Duke 2018; Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001).
- ▶ Traditionally used in Ayurveda as Rasayana (rejuvenative tonic) (Sudarshan 2005; Murthy 2004; Kapoor 2001; Gogte 2000).
- ▶ Traditionally used in Ayurveda to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia) (Warrier et al. 2003; API 2001; Gogte 2000).
- ▶ Traditionally used in Ayurveda as a digestive tonic to increase appetite and aid in digestion (stomachic) (Paranjpe 2005; Sidarshan 2005; Warrier et al. 2003; Kapoor 2001; Gogte 2000; Khory and Katrak 1999).
- ▶ Traditionally used in Ayurveda as a laxative for the relief of occasional constipation (Paranjpe 2005; Sudarshan 2005; Warrier et al. 2003; Kapoor 2001; Gogte 2000; Khory and Katrak 1999).

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 Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

Antioxidant

Not to exceed 6 grams of dried fruit, per day (Williamson 2002; API 2001; Kapoor 2001; Gogte 2000).

Amlapitta, Digestive tonic, Laxative, or Rasayana

3-6 grams of dried fruit, per day (Williamson 2002; API 2001; Kapoor 2001; Gogte 2000).



Direction(s) for use

All products

Take 2 hours before or after taking other medications (HC 2009; Martindale 2008).

Laxative

Allow at least 6 to 12 hours for laxative effect to occur (APhA 2002).

Duration(s) of use

Laxative

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (HC 2009; Pray 2006; CPhA 2002).

Risk information

Caution(s) and warning(s)

All products

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if you have or develop abdominal pain, nausea, fever or vomiting (HC 2009; McGuffin et al. 1997).

Amlapitta, Digestive tonic or Laxative

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

Contraindication(s)

No statement required.

Known adverse reaction(s)

Amlapitta, Antioxidant, Digestive tonic, or Rasayana

Stop use if laxative effect occurs.



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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