

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

Date November 27, 2012

Proper name(s)

Phyllanthus emblica L. (Phyllanthaceae [also placed in Euphorbiaceae]) (USDA 2005; McGuffin et al. 2000)

Synonym: *Emblica officinalis* Gaertn. (Phyllanthaceae [also placed in Euphorbiaceae]) (ITIS 2011; API 2001[1990])

Common name(s)

- ▶ Amalaki (Martindale 2011; API 2001[1990]; McGuffin et al. 2000)
- ▶ Amla (Martindale 2011; USDA 2005; API 2001[1990]; McGuffin et al. 2000)
- ▶ Emblic (ITIS 2011; Martindale 2011; USDA 2005)
- ▶ Emblic myrobalan (Martindale 2011; USDA 2005; API 2001[1990]; McGuffin et al. 2000)
- ▶ Indian-gooseberry (Martindale 2011; USDA 2005; McGuffin et al. 2000)

Source material(s)

fruit (API 2001[1990]; Khory and Katrak 1999 [1903])

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

- ▶ Provides antioxidants (Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001; Duke 1992)
- ▶ 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[1990]; 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 [1903]).
- ▶ 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 [1903]).

Dose(s) Statement(s) to the effect of

Sub-population(s)

adults (≥ 19 years)

Quantity(ies)

Amlapitta, Digestive tonic, Laxative, or Rasayana:

3-6 g powdered dried fruit, per day (Williamson 2002; API 2001[1990]; Kapoor 2001; Gogte 2000).

Antioxidant:

Up to 6 g powdered dried fruit, per day (Williamson 2002; API 2001[1990]; Kapoor 2001; Gogte 2000).

Directions for use

Amlapitta, Antioxidant, Digestive tonic, or Rasayana:

Take 2 hours before or after taking other medications (Martindale 2008; HC 1994).

Laxative:

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

Duration of use

Laxative:

- ▶ For occasional use only.
- ▶ For use beyond 7 days, consult a health care practitioner (Pray 2006; CPhA 2002; HC 1994).

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- ▶ If you have or develop abdominal pain, nausea, fever or vomiting, consult a health care practitioner (McGuffin et al. 1997; HC 1994).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Amlapitta, Antioxidant, Digestive tonic, or Rasayana:

Laxative effect may occur, in which case, discontinue use.

Non-medicinal ingredients

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

Storage conditions

No statement required.

Specifications

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

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