AMLA – PHYLANTHUS 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)

- Emblic (ITIS 2011; Martindale 2011; USDA 2005)
- 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).

References cited


References reviewed


Brinker 2010: Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 18]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html


