

# Amla - *Phyllanthus emblica*

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Amla - *Phyllanthus Emblica* (PDF Version - 23.9 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 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 on the label. Date March 28, 2025 Proper name(s), Common name(s), Source information 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) *Phyllanthus emblica* Amalaki Amla Emblic Emblic myrobalan Indian gooseberry Myrobalan *Phyllanthus emblica* Fruit Dry References: Proper name: USDA 2023; Gardner and McGuffin 2013; Common names: ITIS 2023; USDA 2023; API 2001; Gardner and McGuffin 2013; Source information: 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Source of antioxidants/Provides antioxidants (Duke 2023; Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001). Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Duke 2023; 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 mild laxative for the relief of occasional constipation (Paranjpe 2005; Sudarshan 2005; Warrier et al. 2003; Kapoor 2001; Gogte 2000; Khory and Katrak 1999). Traditionally used in Ayurveda as an eye tonic (Chouhan et al. 2013; Premila 2006; Murthy 2004). Note The laxative claim is based on the Ayurvedic Medicine; however, this is not a stimulant laxative nor a bulk-forming laxative. The mode of action is unclear and the laxative effect is mild. The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Traditionally used in Ayurveda to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia) and as a digestive tonic to increase appetite and aid in digestion (stomachic)). For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Amla is traditionally used in Ayurveda as Rasayana (rejuvenative tonic)). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Ethanollic 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, Rasayana or Eye tonic 3-6 grams of dried fruit, per day (Williamson 2002; API 2001; Kapoor 2001; Gogte 2000). Direction(s) for use All products Take a few hours before or after taking other medications or health products (HC 2009). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding (HC 2009). Products providing more than 3 grams of amla, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant (HC 2009). Amlapitta, Digestive tonic Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Laxative Ask 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 (HC 2009; Pray 2006; CPhA 2002). Contraindication(s) Laxative Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) Amlapitta, Antioxidant, Digestive tonic, Rasayana or Eye tonic When using this product you may experience a laxative effect. 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 . 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited API 2001: The Ayurvedic Pharmacopoeia of India, 1 st edition, Part I, Volume I. Delhi (IN): The Controller of Publications; 2001[Reprint of 1990 publication]. Chouhan B, Kumawat RC, Kotecha M, Ramamurthy A, Nathani S. Treiphla: A Comprehensive Ayurvedic Review. International Journal of Research in Ayurveda and Pharmacy; 2013;4(4): 612-617. CPhA 2002: Repchinsky C, editor-in-chief. Patient Self-Care: Helping Patients Make Therapeutic Choices. 1 st edition. Ottawa (ON): Canadian Pharmacists Association; 2002. Duke 2023: Dr. Duke's Phytochemical and Ethnobotanical Databases. [Accessed 2023 December 31]. Available from: <https://phytochem.nal.usda.gov/> Gardner Z. and McGuffin M. editors. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. American Herbal Products Association. Boca Raton (FL): CRC Press; 2013. Gogte VVM. 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Evaluation of Indian Gooseberry (*Emblica officinalis* Gaertn., syn. *Phyllanthus emblica* L.) Supplements. *Phytotherapy Research* 2009;23:1309-1315. Sabu MC, Kuttan R. Anti-diabetic activity of medicinal plants and its relationship with their antioxidant property. *Journal of Ethnopharmacology* 2002;81(2):155-169. Sawant L, Pandita N, Prabhakar B. Determination of gallic acid in *Phyllanthus emblica* Linn. dried fruit powder by HPTLC. *Journal of Pharmacy and BioAllied Sciences* 2010;2(2):105-108. Scartezzini P, Speroni E. Review on some plants of Indian traditional medicine with antioxidant activity. *Journal of Ethnopharmacology* 2000;71:23-42. Report a problem on this page Date modified: 2019-03-01

## **DOSAGE FORM(S)**

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

## **RISK INFORMATION**

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding (HC 2009). Products providing more than 3 grams of amla, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant (HC 2009). Amlapitta, Digestive tonic Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Laxative Ask 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 (HC 2009; Pray 2006; CPhA 2002). Contraindication(s) Laxative Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) Amlapitta, Antioxidant, Digestive tonic, Rasayana or Eye tonic When using this product you may experience a laxative effect.

## **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 CONDITION(S)**

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## **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.

| Proper name(s)      | Common name(s)   | Source information  |       |     |
|---------------------|--|---------------------|-------|-----|
| Source material(s)  | Part(s)  | Preparation(s)      |       |     |
| Phyllanthus emblica | AmalakiAmlaEmblicEmblic myrobalanIndian gooseberryMembolan | Phyllanthus emblica | Fruit | Dry |