



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 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)
<i>Phyllanthus emblica</i>	<ul style="list-style-type: none"> • Amalaki • Amla • Emblic • Emblic myrobalan • Indian gooseberry • Myrobalan 	<i>Phyllanthus emblica</i>	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).

Notes

- 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 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, 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.

Product Facts	
Medicinal ingredient in each capsule <i>Phyllanthus emblica</i> (Amla – fruit)	XX mg
Uses	
<ul style="list-style-type: none"> • Source of antioxidants that help protect cell against free radicals. • Traditionally used in Ayurveda as Rasayana (rejuvenative tonic). • Traditionally used in Ayurveda to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia). • Traditionally used in Ayurveda as a digestive tonic to increase appetite and aid in digestion (stomachic). • Traditionally used in Ayurveda as a mild laxative for the relief of occasional constipation. • Traditionally used in Ayurveda as an eye tonic. 	
Warnings	
If applicable¹:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Do not use if you have fever or any undiagnosed gastrointestinal trouble².	
Ask a health care practitioner before use if you are pregnant³ • you are breastfeeding.	
When using this product you may experience a laxative effect.	
Ask a health care practitioner if • symptoms persist or worsen • if laxative effect does not occur within 7 days².	
Directions	
Adults 18 years and older: • Take X capsule(s), X time(s) a day • Take a few hours before or after taking other medications or health products.	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame.

²The qualifier ‘For constipation relief:’ may be included on the label to inform consumers.

³Products providing more than 3 g of amla, per day.

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