

NATURAL HEALTH PRODUCT

TRIPHALA

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.
- ▶ The name "Triphala" is restricted to combination that contains the three medicinal ingredients indicated in Table 1. Therefore, brand name and use or purpose can only mention the name Triphala if these three medicinal ingredients are present in the product.

Date

February 25, 2019

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 myrobolan ▶ Indian gooseberry ▶ Myrobolan 	<i>Phyllanthus emblica</i>	Fruit	Dried
<i>Terminalia chebula</i>	<ul style="list-style-type: none"> ▶ Harad ▶ Haritaki 	<i>Terminalia chebula</i>	Fruit	Dried
<i>Terminalia bellirica</i>	<ul style="list-style-type: none"> ▶ Beach-almond ▶ Beleric myrobolan ▶ Belleric ▶ Belleric myrobolan ▶ Bibhitaki ▶ Bohera ▶ Myrobolan 	<i>Terminalia bellirica</i>	Fruit	Dried

References: Proper names: IT IS 2018, USDA 2018, API 2001, McGuffin et al. 2000; Common names: ITIS 2018, USDA 2018, Martindale 2011, API 2001, McGuffin et al. 2000; Source information: API 2001, Kapoor 2001, Khory and Katrak 1999, Nadkarni 1954.



Route of administration

Oral

Dosage form(s)

This monograph is not intended to include 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)

All products

- ▶ Traditionally used in Ayurveda as a laxative for the relief of occasional constipation (Chouhan et al. 2013; Murthy 2004).
- ▶ Traditionally used in Ayurveda as an eye tonic (Chouhan et al. 2013; Murthy 2004).

Products containing Triphala and/or Amalaki and/or Haritaki

- ▶ Traditionally used in Ayurveda as Rasayana (rejuvenative tonic) (Murthy 2004; API 2001; Nadkarni 1976).
- ▶ Traditionally used in Ayurveda as a digestive tonic to promote digestive fire, increase appetite and aid in digestion (stomachic) (Paranjpe 2005; Sudarshan 2005; Warriar et al. 2003; Kapoor 2001; Gogte 2000; Khory and Katrak 1999).

Products containing Amalaki

- ▶ Traditionally used in Ayurveda to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia) (Warriar et al. 2003; API 2001; Gogte 2000).
- ▶ Source of/Provides antioxidants (Duke 2018, Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001).

Products containing Haritaki and/or Bibhitaki

- ▶ Traditionally used in Ayurveda to help expel intestinal worms (vermifuge) (Sukh Dev 2006; Kirtikar and Basu 1981; Nadkarni 1954).
- ▶ Traditionally used in Ayurveda to help relieve cough (Sukh Dev 2006; API 2001).



Products containing Haritaki

Traditionally used in Ayurveda to help relieve colic pain and flatulence (carminative) (Sukh Dev 2006; Khare 2004).

Permitted combinations

All ingredients included in this monograph may be combined together as long as combined dose is within the dose limits indicated below.

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation

Adults 18 years and older

Quantity(ies)

Antioxidants

Methods of preparation: Dry, Powder, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

Not to exceed 6 grams of Amalaki, per day (API 2001).

Rasayana; Digestive tonic; Eye tonic

Methods of preparation: Dry, Powder, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

Table 2: Dose information presented as dose per day

Medicinal Ingredients	Dried fruit (grams/day)	
	Minimum	Maximum
Amalaki	3	6
Haritaki	1	3
Bibhitaka	1	3
Amalaki + Haritaki + Bibhitaki (Triphala)	1	3
Amalaki + Haritaki or Bibhitaki	2	3
Haritaki + Bibhitaki	1	3

References: Amalaki: API 2001; Haritaki: Williamson 2002, API 2001, Gogte 2000; Bibhitaki: Williamson 2002, API 2001, Gogte 2000; Triphala: Tillostn et al. 2001, Gogte 2000; Amalaki + Haritaki or Bibhitaki: API 2001, Gogte 2000; Haritaki + Bibhitaki: Tillostn et al. 2001, Gogte 2000.



Laxative; Amlapitta; Carminative; Cough; Vermifuge

Methods of preparation: Dry, Powder, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

Table 3: Dose information presented as dose per day

Medicinal Ingredients	Dried fruit (grams/day)	
	Minimum	Maximum
Amalaki	3	6
Haritaki	2	6
Bibhitaka	3	6
Amalaki + Haritaki + Bibhitaki (Triphala)	2	6
Any 2 combined together	3	6

References: Amalaki: API 2001; Haritaki: API 2001, Murthy 1994; Bibhitaki: API 2001; Triphala (Amalaki +Haritaki + Bibhitaki): Tillostion et al. 2001, Murthy 1994; Any 2 combined together: Murthy 1994.

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; Vermifuge

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

Vermifuge

For occasional use only.

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, breastfeeding or if you have abdominal pain,



nausea, fever or vomiting (HC 2009; McGuffin et al. 1997).

- ▶ Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhoea (Murthy 2004; McGuffin et al. 1997).

Amlapitta; Stomachic; Laxative; Cough; Carminative; Vermifuge

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

Products providing more than 4 g of Triphala dried fruit or more than 4 g of Haritaki dried fruit

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications, thiazide diuretics, corticosteroids, licorice root or other medications or health products which may aggravate electrolyte imbalance (Murthy 2004; McGuffin et al. 1997).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a kidney disorder (McGuffin et al. 1997).

Contraindication(s)

Products providing more than 4 g of Triphala dried fruit or more than 4 g of Haritaki dried fruit

Do not use this product if you have abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease such as Crohn's disease or ulcerative colitis, abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes (Murthy 2004; McGuffin et al. 1997).

Known adverse reaction(s)

All products except those making laxative claim

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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