NATURAL HEALTH PRODUCT

HOLY BASIL – OCIUMUM TENUIFLORUM – LEAF

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

September 29, 2015

Proper name(s)

Ocimum tenuiflorum L. (Lamiaceae) (USDA 2007; McGuffin et al. 2000)

Common name(s)

► Holy basil (USDA 2007; McGuffin et al. 2000)
► Sacred basil (USDA 2007; McGuffin et al. 2000)
► Tulasi (McGuffin et al. 2000; API 1999)
► Tulsi (USDA 2007; McGuffin et al. 2000; API 1999)

Source material(s)

Leaf (API 1999; Agrawal et al. 1996)

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**

- Traditionally used in Ayurveda (as an expectorant and/or demulcent) to help relieve cough (Kasa) and colds (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991).


- Traditionally used in Ayurveda as a cardiotonic (Hrdya) (Paranjpe 2005; Sudarshan 2005; Murthy 2004; Warrier 2003; Williamson 2002; Gogte 2000; API 1999).


- Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (in case of mental and physical fatigue related to stress) (McIntyre 2011; Winston and Maimes 2007; Hoffman 2003; Williamson 2003).

- Source of/Provides antioxidants (Hakkim et al. 2007; Winston and Maimes 2007; Williamson 2003).

**Note**

A claim for traditional use must include the term “Herbal Medicine” or “Ayurvedic Medicine/Ayurveda”.
**Dose(s)**

Statement(s) to the effect of

**Subpopulation(s)**

Adults (≥ 19 years)

**Quantity(ies)**

Ayurveda

Decoction, infusion, and non-standardized aqueous extract:
7 – 28 g dried leaf, per day (Williamson 2002; Kapoor 2001).

Adaptogen

Decoction, infusion, and non-standardized aqueous extract:
4.2 – 28 g dried leaf, per day (Winston and Maimes 2007; Williamson 2002; Kapoor 2001).

All claims

Powder, extract dry, extract liquid, fluid extract, tincture:
2 – 3 g dried leaf, per day (API 1999).

Antioxidant

Decoction, infusion, and non-standardized aqueous extract:
Not to exceed 28 g dried leaf, per day (Williamson 2002; Kapoor 2001).

Powder, extract dry, extract liquid, fluid extract, tincture:
Not to exceed 3 g dried leaf, per day (API 1999).

**Duration of use**

No statement required.
Risk information
Statement(s) to the effect of

Caution(s) and warning(s)

All products:
- If you are breastfeeding, consult a health care practitioner prior to use (WHO 2002).
- If you are taking any heart or blood pressure medication, consult a health care practitioner prior to use (Rai et al. 1997; Agrawal et al. 1996).
- If you have a heart condition or diabetes, consult a health care practitioner prior to use (Rai et al. 1997; Agrawal et al. 1996).

Relief of cough and Digestive aid:
If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

If you are pregnant, do not use this product (Prakash et al. 2005; Ahmed et al. 2002; WHO 2002; Wohlmuth 2002; Kapoor 2001).

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

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

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
References cited


References reviewed


Bradley P. British Herbal Compendium – A handbook of scientific information on widely used plant drugs. (Volume 2) Bournemouth (GB): British Herbal Medicine Association; 2006.


