NATURAL HEALTH PRODUCT

OLIVE LEAF – *Olea europaea*

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**

December 8, 2015

**Proper name(s)**

*Olea europaea* L. (USDA 2004)

**Common name(s)**

Olive leaf (EMA 2012; USDA 2014)

**Source material(s)**

Leaf (EMA 2012; Jemai et al. 2009)

**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

- Source of antioxidants/Provides antioxidants (Jemai et al. 2009; Andreadou et al. 2006).
- Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effects of/the oxidative damage caused by/cell damage caused by) free radicals (Jemai et al. 2009; Andreadou et al. 2006).
- Used in Herbal Medicine as a diuretic (EMA 2012; Bone 2003).

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Antioxidant

Dry, powder, tincture, fluid extract
Up to 3.5 g dried leaf per day (Bone 2003).

Decoction
- Up to 5 g dried leaves per single dose; not to exceed 10 g dried leaves per day (EMA 2012).
- Up to 10 g fresh leaves per single dose; not to exceed 20 g fresh leaves per day (EMA 2012).

Directions for use:
Add dried or fresh leaves to 150 ml of boiling water. Allow to simmer to reach 100 ml. Strain before drinking. To be consumed hot (morning and evening) (EMA 2012).

Infusion
Up to 7-8 g dried leaves per single dose not to exceed 30 g dried leaves per day (EMA 2012).

Directions for use:
Add dried leaves to 150 ml of boiling water. Allow to steep for 30 minutes. Strain before drinking.

All standardized extracts
Up to 500 mg extract per day (up to 3.5 g dried leaves per day) (Perrinjaquet-Moccetti et al. 2008).

Potency:
Up to 20.8% oleuropein (Perrinjaquet-Moccetti et al. 2008).

Diuretic
Dry, powder, tincture, fluid extract
0.6 – 3.5 g dried leaves per day (EMA 2012; Bone 2003).

Decoction
- 5 g dried leaves per single dose not to exceed 10 g dried leaves per day (EMA 2012).
- 10 g fresh leaves per single dose not to exceed 20 g fresh leaves per day (EMA 2012).

Directions for use:
Add dried or fresh leaves to 150 ml of boiling water. Allow to simmer to reach 100 ml. Strain before drinking. To be consumed hot (morning and evening) (EMA 2012).

Infusion
7 – 8 g dried leaves per single dose; not to exceed 30 g dried leaves per day (EMA 2012).

Directions for use:
Add dried leaves to 150 ml of boiling water. Allow to steep for 30 minutes. Strain and consume.

All products
Directions for use:
Take with food (Bone 2003).

Duration of use
Statement(s) to the effect of

Diuretic
For occasional use only (APhA 2002; CPhA 2002).

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 (EMA 2012).
- If you are taking other diuretics, consult a health care practitioner prior to use (EMA 2012).
- If you have a kidney disorder, consult a health care practitioner prior to use (EMA 2012).

Contraindication(s)
No statement required.

Known adverse reaction(s)
Allergic reactions can occur in people allergic to plants of the Oleaceae family (EMA 2012).
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 Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited


**References reviewed**


