

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 statements are synonymous. Either term or statement may be selected by the applicant.

Date

December 18, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Olea europaea</i>	Olive leaf	<i>Olea europaea</i>	Leaf	<ul style="list-style-type: none"> ▶ Dried ▶ Fresh

References: Proper name: USDA 2018; Common name: USDA 2018, EMA 2017; Source material: EMA 2017, Jemai et al. 2009.

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 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)

- ▶ Source of/Provides antioxidants (Jemai et al. 2009; Andreadou et al. 2006).
- ▶ Used in Herbal Medicine as a diuretic (EMA 2017; Bone 2003).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidant

Methods of preparation: Dry, Powder, Non-Standardized Ethanolic Extract (Dry extract, Tincture, Fluid extract)

Not to exceed 3.5 grams of dried leaf, per day (Bone 2003).

Methods of preparation: Standardised Ethanolic Extract (Dry extract, Tincture, Fluid extract)

Not to exceed 3.5 grams of dried leaf, per day and 20.8 % oleuropein (Perrinjaquet-Moccetti et al. 2008; Bone 2003).

Method of preparation: Decoction

- ▶ Not to exceed 10 grams of dried leaves, per day and 5 grams per single dose (EMA 2017).
- ▶ Not to exceed 20 grams of fresh leaves, per day and 10 grams per single dose (EMA 2017).

Method of preparation: Decoction standardised

- ▶ Not to exceed 10 grams of dried leaves per day, 5 grams per single dose and 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).
- ▶ Not to exceed 20 grams of fresh leaves per day, 10 grams per single dose and 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).

Method of preparation: Infusion

Not to exceed 30 grams of dried leaves, per day and 8 grams per single dose (EMA 2017).

Method of preparation: Infusion standardised

Not to exceed 30 grams of dried leaves, per day, 8 grams per single dose and 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).



Diuretic

Methods of preparation: Dry, Powder, Non-Standardized Ethanolic Extract (Dry extract, Tincture, Fluid extract)

0.6 - 3.5 grams of dried leaves, per day (EMA 2017; Bone 2003).

Methods of preparation: Standardised Ethanolic Extract (Dry extract, Tincture, Fluid extract)

0.6 - 3.5 grams of dried leaves, per day and not to exceed 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008; Bone 2003).

Method of preparation: Decoction

- ▶ 5 grams of dried leaves, 1 to 2 times per day (EMA 2017).
- ▶ 10 grams of fresh leaves, 1 to 2 times per day (EMA 2017).

Method of preparation: Decoction standardised

- ▶ 5 grams of dried leaves, 1 to 2 times per day and not to exceed 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).
- ▶ 10 grams of fresh leaves, 1 to 2 times per day and not to exceed 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).

Method of preparation: Infusion

7 - 8 g dried leaves, 1 to 3 times per day (EMA 2017).

Method of preparation: Infusion standardised

7 - 8 g dried leaves, 1 to 3 times per day and not to exceed 20.8 % oleuropein (EMA 2017; Perrinjaquet-Moccetti et al. 2008).

Note

For standardized extracts, as evidence mainly supports the quantity crude equivalent of olive leaves, both the quantity crude equivalent and the maximum concentration of the potency constituent must be met.

Direction(s) for use

Take with food (Bone 2003).



Duration(s) of use

Diuretic

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

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 pregnant, breastfeeding or have a kidney disorder (EMA 2017).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking other diuretics (EMA 2017).

All products except those making a diuretic claim

Diuretic effect may occur.

Contraindication(s)

No statement required.

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.

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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