

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 label at the applicant's discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

Date

December 19, 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>Olea europaea</i>	Olive leaf	<i>Olea europaea</i>	Leaf	- Dry - Fresh

References: Proper name: USDA 2024; Common name: USDA 2024; EMA 2017; Source information: 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 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 (Jemai et al. 2009; Andreadou et al. 2006).



- 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 (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, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

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

Methods of preparation: Standardized Ethanolic Extracts (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).

Methods of preparation: Decoction, Decoction concentrate

- 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).

Methods of preparation: Decoction standardized, Decoction concentrate standardized

- 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).

Methods of preparation: Infusion, Infusion concentrate

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

Methods of preparation: Infusion standardized, Infusion concentrate standardized

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, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

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

Methods of preparation: Standardized Ethanolic Extracts (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).

Methods of preparation: Decoction, Decoction concentrate

- 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).

Methods of preparation: Decoction standardized, Decoction concentrate standardized

- 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).

Methods of preparation: Infusion, Infusion concentrate

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

Methods of preparation: Infusion standardized, Infusion concentrate standardized

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

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you pregnant or breastfeeding (EMA 2017).**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder (EMA 2017).**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking other diuretics (EMA 2017).**

Contraindication(s)

No statement required.

Known adverse reaction(s)

All products except those making a diuretic claim

When using this product diuretic effect may occur.

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>Olea europaea</i> (Olive leaf) X:1 extract XX mg Equivalent to YY g dried leaf; Providing 20.8% oleuropein
Uses • Source of antioxidants. • Used in Herbal Medicine as a diuretic.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Ask a health care practitioner before use if • you are pregnant or breastfeeding • you have a kidney disorder • you are taking other diuretics.
When using this product diuretic effect may occur ² .
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take with food • As a diuretic: For occasional use only.
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.

²All products except those making a diuretic claim.

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