



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

Andreadou I, Iliodromitis EK, Mikros E, Constantinou M, Agalias A, Magiatis P, Skaltsounis AL, Kamber E, Kremastinos DH. The olive constituent oleuropein exhibits anti-ischemic, antioxidative, and hypolipidemic effects in anesthetized rabbits. *Journal of Nutrition and Disease* 2006;136(8):2213-9.

APhA 2002: Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. *Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care*. 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

Bone K. *A Clinical Guide to Blending Liquid Herbs: Herbal Formulations for the Individual Patient*. St. Louis (MO): Elsevier Churchill Livingstone; 2003.

BP 2013: *British Pharmacopoeia 2013. Volume IV*. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA); 2010.

CPhA 2002: Canadian Pharmacists Association. *Patient Self-Care. Helping Patients Make Therapeutic Choices*. Ottawa (ON): Canadian Pharmacists Association; 2002.

de Bock M, Derraik JGB, Brennan CM, Biggs JB, Morgan PE, Hodgkinson SC, Hofman PL, Cutfield WS. Olive (*Olea europaea* L.) leaf polyphenols improve insulin sensitivity in middle-aged overweight men: a randomized, placebo-controlled, crossover trial. *PLoS ONE* 8(3):e57622. doi: 10.1371/journal.pone.0057622



EMA 2012: European Medicines Agency. Community herbal monograph on *Olea europaea* L., folium. [Accessed 2014 April 1]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2012/04/WC500125461.pdf

Jemai H, El Feki A, Sayadi S. Antidiabetic and antioxidant effects of hydroxytyrosol and oleuropein from olive leaves in alloxan-diabetic rats. *Journal of Agriculture and Food Chemistry* 2009;57(19):8798-8804.

Perrinjaquet-Moccetti T, Busjahn A, Schmidlin C, Schmidt A, Bradl B, Aydogan, C. Food Supplementation with an olive (*Olea europaea* L.) leaf extract reduces blood pressure in borderline hypertensive monozygotic twins. *Phytotherapy Research* 2008;22(9):1239-1242.

Ph.Eur. 2011: European Pharmacopoeia, 7th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM); 2011.

Susalit E, Agus N, Effendi I, Tjandrawinata RR, Nofiarny D, Perrinjaquet-Moccetti T, Verbruggen M. Olive (*Olea europaea*) leaf extract effective in patients with stage-1 hypertension: Comparison with Captopril. *Phytomedicine* 2011;18:251-258

USDA 2004: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [Internet]. Beltsville (MD). [*Olea europea* L. Last updated 2004 January 29; Accessed 2014 June 20]. Available from: <http://www.ars-grin.gov/cgi-bin/npgs/html/taxon.pl?25555>

Wainstein J, Ganz T, Boaz M, Bar Dayan Y, Dolev E, Kerem Z, Madar Z. Olive leaf extract as a hypoglycemic agent in both human diabetic subjects and in rats. *Journal of Medicinal Food* 2012;15(7):605-610.

References reviewed

Abaza L, Ben Youssef N, Manai H, Mahjoub Haddad F, Methenni K, Zarrouk M. Chétoui olive leaf extracts: influence of the solvent type on phenolics and antioxidant activities. *Grasas y Aceites* 2011;62(1):96-104

Blumenthal M. *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines*. Austin (TX): American Botanical Council in cooperation with Integrative Medicine Communications; 1998.

Brinker F. *Herb Contraindications and Drug Interactions*, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

Cherif S, Rahal N, Haouala M, Hizaoui B, Dargouth F, Gueddiche M, Kallel Z, Balansard G, Boukef K. Essai clinique d'un extrait titré de feuilles d'olivier dans le traitement de l'hypertension artérielle essentielle. *Journal de pharmacie de Belgique* 1996;51(2):101-124.

de Bock M, Thorstensen EB, Derraik JGB, Henderson HV, Hofman PL, Cutfield WS. Human absorption and metabolism of oleuropein and hydroxytyrosol ingested as olive (*Olea europaea* L.) leaf extract. *Molecular Nutrition and Food Research* 2013;57(11):2079-2085.

EFSA 2011: European Food Safety Authority. Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), “anti-inflammatory properties” (ID 1882), “contributes to the upper respiratory tract health” (ID 3468), “can help to maintain a normal function of gastrointestinal tract” (3779), and “contributes to body defences against external agents” (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), European Food Safety Authority (EFSA), Parma, Italy. [Accessed 2014 July 9]. Available from: <http://www.efsa.europa.eu/en/efsajournal/pub/2033.htm>

El SN, Karakaya S. Olive tree (*Olea europaea*) leaves: potential beneficial effects on human health. *Nutrition Reviews* 2009;67(11):632-638.

EMA 2012: European Medicines Agency Assessment report on *Olea europaea* L., folium. EMA Committee on Herbal Medicinal Products [Accessed 2014 Jul 15]. Available from http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/04/WC500125459.pdf

Hoffmann D. *Medical Herbalism: The Science and Practice of Herbal Medicine*. Rochester (VT): Healing Arts Press; 2003.

NS 2014: Olive leaf Natural Standard Professional Monograph [Internet]. Natural Standard Inc; 2014. [Accessed 2014 June 20]. Available from: <http://www.naturalstandard.com/>

Skenderi G. *Herbal Vade Mecum*. Rutherford (NJ): Herbacy Press; 2004.

Singh I, Mok M, Christensen AM, Turner AH, Hawley JA. The effects of polyphenols in olive leaves on platelet function. *Nutrition, Metabolism & Cardiovascular Diseases* 2008;18:127-132.

Thorne Research Inc. Monograph: Olive Leaf. *Alternative Medicine Review* 2009;14(1):62-66.

Weiss RF and Fintelmann V. *Herbal Medicine*. 2nd edition. New York (NY): Thieme; 2000.

Williamson EM, Evans FJ, Wren RC. *Potter's Herbal Cyclopaedia: The Authoritative Reference Work on Plants with a Known Medicinal Use*. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003.