Olive leaf - Olea europaea

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OLIVE LEAF - OLEA EUROPAEA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 57 KB) 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 Olea europaea Olive leaf Olea europaea Leaf 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 any age category listed in this monograph for the specified route of administration are listed 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 are 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. 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. 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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 2017: 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. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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 are 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.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		
Olea europaea	Olive leaf	Olea europaea	Leaf	DriedFresh