Feverfew

FEVERFEW - TANACETUM PARTHENIUM 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 - 49.7 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 July 8, 2022 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) Tanacetum parthenium Feverfew Tanacetum parthenium Herb top Leaf Dry References: Proper name: USDA 2019; Common name: McGuffin et al. 2000; Source information: Barnes et al. 2007, Bradley 1992. 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. Digestive aid; Headache relief 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. Migraine prevention; Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic The only acceptable dosage forms are: Capsules; Tablets. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to aid digestion (stomachic) (Williamson 2003; Mills and Bone 2000; Felter and Lloyd 1983). (Traditionally) used in Herbal Medicine to help relieve headaches (Winston and Kuhn 2008; Boon and Smith 2004; Williamson 2003; Cook 1869). (Used in Herbal Medicine to) help(s) prevent migraine headaches (Barnes et al. 2007; Hoffmann 2003; Bradley 1992). (Used in Herbal Medicine to) help(s) reduce the severity and/or frequency of migraine headaches and associated symptoms such as nausea and vomiting, when taken as a prophylactic (Palevitch et al. 1997; Murphy et al. 1988; Johnson et al. 1985). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Digestive aid; Headache relief Methods of preparation: Powdered, Non-Standardized Ethanolic Extracts (Extract dry, Tincture) 50 - 250 milligrams of dried herb top and/or leaf, per day (Barnes et al. 2007; Sweetman 2007; Hoffmann 2003; Williamson 2003; Mills and Bone 2000; Palevitch et al. 1997; Awang 1993; Bradley 1992; Murphy et al. 1988; Johnson et al. 1985). Digestive aid; Headache relief; Migraine prevention; Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic Method of preparation: Powdered standardized 50 - 250 milligrams of dried leaf per day, standardized to 0.2 - 2 % parthenolide (dry weight); Not to exceed 4 milligrams of parthenolide, per day (Awang 2010; (Curry et al. 2004; Hoffmann 2003; Awang 1993). Direction(s) for use All products Take with or after food (Barnes et al. 2007; McGuffin et al. 1997; Johnson et al. 1985). Reduce the dosage gradually if treatment is to be paused or discontinued (ESCOP 2003; Mills and Bone 2000). Duration(s) of Use All products Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 months (Awang 1993). Migraine prevention; Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic Use for at least 4-6 weeks to see beneficial effects (Palevitch et al. 1997; Murphy et al. 1988). Risk Information Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (Brinker 2001; Biggs et al. 1982). Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you are breastfeeding (Boon 2000). Contraindication(s) Do not use this product if you are pregnant (Brinker 2001; McGuffin et al. 1997). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Paulsen et al. 2001; Hausen 1996). Some people may experience sore mouth, mouth ulcers and/or gastrointestinal discomfort (McGuffin et al. 1997; Murphy et al. 1988; Johnson et al. 1985). 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 (NHPR). 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. For migraine prevention and Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic: Products must contain a minimum of 90% dried leaf (Awang 1993). References Cited Awang DVC. Feverfew. In: Coates PM, Betz JM, Blackman MR, Cragg GM, Levine M, Moss J, White JD, editors. Encyclopedia of Dietary Supplements. Second Edition. New York (NY): Informa Healthcare; 2010. p. 267-273. Awang DVC. 1993. Feverfew Fever: A Headache for the Consumer. Herbalgram 29:34-36. Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press. Biggs MJ, Johnson ES, Persaud NP, Ratcliffe DM. 1982. 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Feverfew for preventing migraine (Review). The Cochrane Database of Systematic Reviews, Issue 1. Art. No.: CD002286.pub2. DOI: 10.1002/14651858.CD002286.pub2. Sweetman SC, editor. 2007. Martindale: The Complete Drug Reference, 35th edition. London (GB): Pharmaceutical Press. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. Tanacetum parthenium (L.) Sch. Bip. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2019 June 28] Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx Williamson EM. 2003. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (GB): The C.W. Daniel Company Limited. Winston D, Kuhn MA. 2008. Winston and Kuhn's Herbal Therapy and Supplements: A Scientific and Traditional Approach, 2nd edition. 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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 Must be established in accordance with the requirements described in theNatural Health Products Regulations(NHPR).

DOSAGE FORM(S)

Digestive aid; Headache relief 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. Migraine prevention; Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic The only acceptable dosage forms are: Capsules; Tablets.

DOSE(S)

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme. Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original]. Hausen BM. 1996. A 6-year experience with compositae mix. American Journal of Contact Dermatitis 7(2):94-99. Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press. Johnson ES, Kadam NP, Hylands DM, Hylands PJ. 1985. Efficacy of feverfew as prophylactic treatment of migraine. British Medical Journal 291(6495):569-573. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. Murphy JJ, Heptinstall S, Mitchell JR. 1988. Randomized double-blind placebo-controlled trial of feverfew in migraine prevention. Lancet 2(8604):189-192. Palevitch D, Earon G, Carasso R. 1997. Feverfew (Tanacetum parthenium) as a prophylactic treatment for migraine: a double-blind placebo-controlled study. Phytotherapy Research 11:508- 511. Paulsen E, Anderson KE and Hausen BM. 2001. Sensitization and cross-reaction patterns in Danish Compositae-allergic patients. Contact Dermatitis 45(4):197-204. Pittler MH, Ernst E. 2004. Feverfew for preventing migraine (Review). The Cochrane Database of Systematic Reviews, Issue 1. Art. No.: CD002286.pub2. DOI: 10.1002/14651858.CD002286.pub2. Sweetman SC, editor. 2007. Martindale: The Complete Drug Reference, 35th edition. London (GB): Pharmaceutical Press. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. Tanacetum parthenium (L.) Sch. Bip. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2019 June 28] Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx Williamson EM. 2003. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (GB): The C.W. Daniel Company Limited. Winston D, Kuhn MA. 2008. Winston and Kuhn's Herbal Therapy and Supplements: A Scientific and Traditional Approach, 2nd edition. Philadelphia (PA): Lippincott Williams and Wilkins.

RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (Brinker 2001; Biggs et al. 1982).Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you are breastfeeding (Boon 2000). Contraindication(s) Do not use this product if you are pregnant (Brinker 2001; McGuffin et al. 1997). Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Paulsen et al. 2001; Hausen 1996).Some people may experience sore mouth, mouth ulcers and/or gastrointestinal discomfort (McGuffin et al. 1997; Murphy et al. 1988; Johnson et al. 1985).

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 theNatural Health Products Regulations(NHPR).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations(NHPR).

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.For migraine prevention and Reduction of severity, frequency and symptoms of migraines when taken as a prophylactic: Products must contain a minimum of 90% dried leaf (Awang 1993).

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Tanacetum parthenium	Feverfew	Tanacetum parthenium	Herb topLeaf	Dry