

#### NATURAL HEALTH PRODUCT

#### FEVERFEW - TANACETUM PARTHENIUM

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	Feverfew	Tanacetum	Herb top	Dry
parthenium		parthenium	► Leaf	
parthenium		parthenium	► Leaf	

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: Dry, 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)

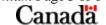
- ► Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (Brinker 2001; Biggs 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).

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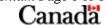
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