25 September 2019
EMA/HMPC/48715/2017
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Tanacetum parthenium* (L.) Schultz Bip., herba

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2009 March 2010 May 2010
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 May 2010
End of consultation (deadline for comments).	15 August 2010
Re-discussion in MLWP	September 2010 November 2010
Adoption by HMPC Monograph (EMEA/HMPC/587578/2009) Assessment Report (EMEA/HMPC/587579/2009) List of references (EMEA/HMPC/587580/2009) Overview of comments received during the public consultation (EMEA/HMPC/563270/2010) HMPC Opinion (EMEA/HMPC/757136/2010)	25 November 2010
First systematic review	
Discussion in HMPC/MLWP	January 2017 November 2017 March 2018 June 2018 September 2018 January 2019 May 2019 July 2019 September 2019
Adopted by HMPC for release for consultation	25 September 2019
Start of public consultation	15 October 2019
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu.	15 January 2020

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Tanacetum parthenium* (L.) Schultz Bip., herba; Tanaceti parthenii herba; feverfew

BG (bulgarski): Моминска вратига, стрък CS (čeština): nať kopretiny řimbaby DA (dansk): Matrem DE (Deutsch): Mutterkraut EL (elliniká): παρθένιον EN (English): feverfew ES (español): Matricaria, partes aéreas de ET (eesti keel): lõhnava neitsikummeli ürt FI (suomi): reunuspäivänkakkara FR (français): grande camomille (parties aériennes de) HR (hrvatski): zelen majčinskog vratića HU (magyar): őszi margitvirág virágos hajtás IT (italiano): Tanaceto (Matricale) parti aeree	LT (lietuvių kalba): Vaistinių skaistenių žolė LV (latviešu valoda): Meiteņu zeltpīpenītes laksti MT (Malti): werqa tal-arċmisa/arċmisa NL (Nederlands): Moederkruid PL (polski): Ziele maruny PT (português): matricária RO (română): iarbă de spilcuţă SK (slovenčina): vňať rimbaby obyčajnej SL (slovenščina): zel belega vratiča SV (svenska): mattram, ört IS (íslenska): Glitbrá NO (norsk): matrem

European Union herbal monograph on *Tanacetum parthenium* (L.) Schultz Bip., herba

1. Name of the medicinal product

To be specified for the individual finished product.

1. Qualitative and quantitative composition[1, 1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC. *Tanacetum parthenium* (L.) Schultz Bip., herba (feverfew) i) Herbal substance Not applicable ii) Herbal preparations Powdered herbal substance

2. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

3. Clinical particulars

3.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in the specified indication

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[1] The material complies with the Ph. Eur. monograph (ref.: 1516).

Well-established use	Traditional use
	exclusively based upon long-standing use.

3.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and Elderly* Single dose: 100 mg of powdered herbal substance once daily or 200 mg of powdered herbal substance three times daily Daily dose: 100 mg–600 mg The daily dosage of 100 mg may be increased until obtaining an effect, not exceeding the daily dose of 600 mg. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If migraine headaches recur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted after 2 months. **Method of administration** Oral use

3.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s) and to other plants of the *Asteraceae* (*Compositae*) family.

3.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health

Well-established use	Traditional use
	care practitioner should be consulted.

3.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

3.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and breast-feeding has not been established. Studies in animals have shown signs of reproductive toxicity (see section 5.3 'Preclinical safety data'). The use is not recommended during pregnancy and lactation. No fertility data available.

3.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

3.8. Undesirable effects

Well-established use	Traditional use
	Gastrointestinal disturbances have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

3.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

4. Pharmacological properties

4.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

4.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

4.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. A single study with oral administration of feverfew in dose of 839 mg/kg bw in pregnant rats showed maternal toxicity and embryotoxicity. The dose of feverfew was 11-fold higher than the maximum human daily dose of 600 mg. However, adequate studies on reproductive toxicity have not been performed. Tests on genotoxicity and carcinogenicity have not been performed.

5. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

6. Date of last revision

25 September 2019