12 May 2023
EMA/HMPC/367011/2021
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Fumaria officinalis* L., herba

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2010 November 2010 January 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
End of consultation (deadline for comments)	15 June 2011
Re-discussion in MLWP	July 2011
Adoption by HMPC Monograph (EMA/HMPC/574766/2010) Assessment Report (EMA/HMPC/576232/2010) List of references (EMA/HMPC/576233/2010) HMPC Opinion (EMA/HMPC/749912/2011)	13 September 2011
Revision	
Discussion in HMPC	July 2021 September 2021 November 2021 January 2022 March 2022 May 2022 July 2022 September 2022
Adopted by HMPC for release for consultation	21 September 2022
End of consultation (deadline for comments)	31 January 2023
Re-discussion in HMPC	March 2023 May 2023
Adoption by HMPC	12 May 2023

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Fumaria officinalis* L., herba, Fumariae herba; fumitory

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

BG (bulgarski): Росопас, стрък CS (čeština): zemědýmová nať DA (dansk): Lægejordrøg DE (Deutsch): Erdrauchkraut EL (elliniká): καπνίτου του φαρμακευτικού πόα EN (English): Fumitory ES (español): fumaria, partes aéreas floridas ET (eesti keel): punandi ürt FI (suomi): peltoemäkki, verso FR (français): fumeterre (parties aériennes fleuries de) HR (hrvatski): zelen obične dimnjače HU (magyar): orvosi füstike virágos hajtás IT (italiano): Fumaria parti aeree	LT (lietuvių kalba): Žvirbliarūčių žolė LV (latviešu valoda): Matuzāles laksti MT (Malti): daħnet l-art NL (Nederlands): Gewone duivekervel PL (polski): Ziele dymnicy PT (português): fumária RO (română): iarbă de fumăriţă SK (slovenčina): vňať zemedymu SL (slovenščina): zel navadne rosnice SV (svenska): jordrök, ört IS (íslenska): NO (norsk): jordrøyk

European Union herbal monograph on *Fumaria officinalis* L., herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Fumaria officinalis* L., herba (fumitory) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3.5-5:1), extraction solvent water d) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V f) Juice of fresh plant

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] The material complies with the Ph. Eur. monograph (ref.: 1869)

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the relief of digestive disturbances, such as feelings of fullness, slow digestion and flatulence. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, Adults and Elderly* a) Comminuted herbal substance Single dose: Herbal tea: 2 g of comminuted herbal substance in 250 ml of boiling water or 1.6 g of comminuted herbal substance in 150 ml of boiling water as herbal infusion Daily dose: 4.8-6.4 g daily, divided in 3-4 doses *Adults and Elderly* b) Powdered herbal substance Single dose: 220 mg Daily dose: up to 1100 mg c) Dry extract Single dose: 250 mg Daily dose: up to 1000 mg d) Liquid extract Single dose: 0.5-2 ml Daily dose: 2-4 ml

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	e) Tincture Single dose: 0.5-1 ml Daily dose: 1-4 ml f) Juice of fresh plant Daily dose: 3.5-4 g For a) The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). For b), c), d), e) and f) 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 the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. To be taken before meals.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Due to possible stimulation on bile secretion Fumariae herba is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary disease. For a) The use in children under 12 years of age has not been established due to lack of adequate data. For b), c), d), e) and f) The use in children and adolescents under 18

Well-established use	Traditional use
	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 care practitioner should be consulted. For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

4.7. 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.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

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

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. 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. Tests on reproductive toxicity and carcinogenicity have not been performed. Adequate tests on genotoxicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 May 2023