EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Fumaria officinalis* L., herba

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 November 2010 January 2011
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BG (bălgarski): Росопас, стрък	LT (lietuvių kalba):
CS (čeština): zemědýmová nať	LV (latviešu valoda): Matuzāles laksti
DA (dansk): Lægejordrøg	MT (malti):
DE (Deutsch): Erdrauchkraut	NL (nederlands): gewone duivekervel
EL (elliniká): Πόα καπνίτου του φαρμακευτικού	PL (polski): Ziele dymnicy
EN (English): fumitory	PT (português): Fumária
ES (espanol): Fumaria, partes aéreas floridas	RO (română): iarbă de fumăriţă
ET (eesti keel): punandi ürt	SK (slovenčina): Zemedymová vňať
FI (suomi):	SL (slovenščina): zel navadne rosnice
FR (français): Fumeterre (parties aériennes fleuries de)	SV (svenska): Jordrök
HU (magyar): Orvosi füstike virágos hajtás	IS (íslenska):
IT (italiano): Fumaria parti aeree	NO (norsk): jordrøyk

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Community 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 as amended *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 the 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 the European Pharmacopoeia full standard term.

[1] The dried material complies with the Ph. Eur. monograph (ref.: 07/2010:1869)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used to increase bile flow for the relief of symptoms of indigestion (such as sensation of fullness, flatulence and slow digestion). The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* a) Comminuted herbal substance Herbal tea: 2 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion 1-2 times daily Daily dose: 2-4 g 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 4 times daily d) Liquid extract Single dose: 0.5-2 ml Daily dose: 2-4 ml e) Tincture Single dose: 0.5-1 ml Daily dose: 1-4 ml f) Juice of the fresh plant Daily dose: 3.5-4 g The use in children and adolescents under 18

[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
	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(s). Obstructions of bile ducts, cholangitis, gallstones and any other biliary diseases and hepatitis.

4.4. 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 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 as amended.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c (1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

13 September 2011