2 February 2016
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Origanum majorana* L., herba

Draft

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Re-discussion in MLWP	
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BG (bulgarski): Майорана, стрък CS (čeština): dobromyslová nať DA (dansk): Havemerian DE (Deutsch): Majorankraut EL (elliniká): Πόα οριγανον το αμάρακον EN (English): Majoram ES (español): Mejorana, partes aéreas de ET (eesti keel): majoraaniürt FI (suomi): maustemeirami, verso FR (français): Marjolaine (sommité fleurie de) HR (hrvatski): mažuranova zelen HU (magyar): majoránna virágos hajtás IT (italiano): Maggiorana parti aeree fiorite	LT (lietuvių kalba): Kvapiųjų mairūnų žolė LV (latviešu valoda): Majorāna laksts MT (Malti): ħaxixa tal-Merdqux NL (Nederlands): Echte marjolein, kruid PL (polski): Ziele majeranku PT (português): Manjerona RO (română): iarbă de măghiran SK (slovenčina): Vňať majoránu záhradného SL (slovenščina): zel majarona SV (svenska): Mejram, ört IS (íslenska): NO (norsk): Merian

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

European Union herbal monograph on *Origanum majorana* 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 *Origanum majorana,* herba (Majoram) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Extract[3] (ratio of herbal substance to extraction solvent 1:5), extraction solvents ethanol 96% V/V and white petroleum jelly.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in semi-solid dosage forms for cutaneous use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.
[3] The preparation is described in the Farmakopea Polska (1995), two parts of comminuted *Origanum majorana* L., herba is moistened with one part of ethanol 96% and then warm extracted with ten parts of white petroleum jelly until ethanol evaporation.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used for the symptomatic relief of mild spasmodic gastro-intestinal complaints such as bloating and flatulence. Indication 2) Traditional herbal medicinal product used for relief of irritated skin around the nostrils. 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[4]

Well-established use	Traditional use
Posology	**Posology** Indication 1) *Adults and elderly* a) Herbal tea: 1-2 g of the comminuted herbal substance in one cup (150 ml) boiling water as herbal infusion, one cup, before meals. Daily dose: 3-6 g Indication 2) Herbal preparation b) *Children 1-11 years*, *adolescents* and *adults* Small amount of the preparation spread around nostrils, 2 to 4 times daily (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) If the symptoms persist after 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be

[4] 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
	consulted. Indication 2) If the symptoms persist after 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted **Method of administration** Preparation a) Oral use. Preparation b) Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other plants of the Lamiaceae family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indication 2) The use in children under 1 year of age has not been established due to lack of adequate data. The deep penetration of the ointment inside nostril should be avoided, as it can reduce the activity of the ciliary epithelium If signs of skin infection are observed during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Eye contact with unwashed hands after the application may potentially cause irritation.

Well-established use	Traditional use
	Indication 1) and 2) If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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 ability to drive or 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[5]

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

2 February 2016

[5] Where herbal preparations from *Origani majoranae herba* are used, the total exposure to hydroquinone derivatives should be considered from a safety standpoint.