



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 November 2012  
EMA/HMPC/524621/2011  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Levisticum officinale* Koch, radix

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	July 2011 September 2011 November 2011 January 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 March 2012
End of consultation (deadline for comments).	15 August 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	September 2012
Adoption by Committee on Herbal Medicinal Products (HMPC)	20 November 2012

<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Levisticum officinale</i> Koch, radix; Levistici radix; Lovage root
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BG (bългарski): Селим, корен CS (čeština): Libečkový kořen DA (dansk): Løvestikkerod DE (Deutsch): Liebstöckelwurzel EL (elliniká): Ρίζα λυγιστικού EN (English): Lovage root ES (español): Levístico, raíz de ET (eesti keel): Leeskputkejuur FI (suomi): Liperi, juuri FR (français): Livèche (racine de) HU (magyar): Lestyányökér IT (italiano): Levistico radice	LT (lietuvių kalba): Gelsvių šaknys LV (latviešu valoda): Lupstāja saknes MT (malti): Għerq tal-Levistiku NL (nederlands): Lavaswortel PL (polski): Korzeń lubczyka PT (português): Levístico, raiz RO (română): SK (slovenčina): Ligurčekový koreň SL (slovenščina): Korenina luštreka SV (svenska): Libbstickerot IS (islenska): NO (norsk): Løpestikkerot
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# Community herbal monograph on *Levisticum officinale* Koch, radix

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2</sup>

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Levisticum officinale</i> Koch, radix (lovage root) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

## 3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.

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

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2013:1233).

#### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly</i></p> <p>Herbal tea</p> <p>Single dose: 2 - 3 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion, twice daily.</p> <p>Average daily dose: 4 - 6 g</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>Not to be used for more than 2 - 4 weeks.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance and to other plants of the Apiaceae (Umbelliferae) family or to anethole.</p>

#### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice.</p> <p>If complaints or symptoms such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

<sup>3</sup> 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).

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

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### **4.6. Fertility, pregnancy and lactation**

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

#### **4.7. Effects on ability to drive and use machines**

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

#### **4.8. Undesirable effects**

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

#### **4.9. Overdose**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

<b>Well-established use</b>	<b>Traditional use</b>
	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.  Adequate 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

20 November 2012