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

Community herbal monograph on *Levisticum officinale* Koch, radix

Draft

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| BG (bългарски): Селим, корен CS (čeština): Libečkový kořen DA (dansk): Løvestikkerod DE (Deutsch): Liebstöckelwurzel EL (ελληνικά): 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): LV (latviešu valoda): Lupstāja saknes MT (malti): 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 (íslenska): 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^{1,2}

| 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 a) 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. |

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.: 01/2008:1233 corrected 6.0).

4.2. Posology and method of administration³

| Well-established use | Traditional use |
|----------------------|---|
| | <p>Posology</p> <p><i>Adults and elderly</i></p> <p>a) 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>Duration of use</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>Method of administration</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> |

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).

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. |

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. 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

27 March 2012