



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch, radix

Draft

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Glycyrrhiza glabra</i> L. and/or <i>Glycyrrhiza inflata</i> Bat. and/or <i>Glycyrrhiza uralensis</i> Fisch, radix; liquorice root
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BG (bългарски): Сладник CS (čeština): Lékořicový kořen DA (dansk): Lakridsrod, uskrællet DE (Deutsch): Süßholzwurzel EL (elliniká): Γλυκύρριζα EN (English): Liquorice, root ES (español): Regaliz, raíz de ET (eesti keel): Magusjuurejuur FI (suomi): FR (français): Réglisse (racine de) HU (magyar): Édesgyökér IT (italiano): Liquirizia, radice	LT (lietuvių kalba): LV (latviešu valoda): Lakricu saknes MT (malti): Għerq ta' Ghud is-Sus NL (nederlands): Zoethoutwortel PL (polski): Korzeń lukrecji PT (português): Alcaçuz, raiz RO (română): Rădăcină de lemn dulce SK (slovenčina): Sladkovkový koreň SL (slovenščina): Korenina golostebelnega sladkega korena SV (svenska): Lakritsrot <i>IS (íslenska):</i> <i>NO (norsk):</i> Lakrisrot, uskrelt
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Community herbal monograph on *Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch, 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Glycyrrhiza glabra</i> L. and/or <i>Glycyrrhiza inflata</i> Bat. and/or <i>Glycyrrhiza uralensis</i> Fisch, radix (liquorice root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Soft extract (DER 1:0.4-0.5), extraction solvent water</p> <p>c) Soft extract (DER 3:1), extraction solvent water</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as a herbal tea for oral use.</p> <p>Herbal preparations in liquid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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.: 01/2010: 0277).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1</p> <p>Traditional herbal medicinal product for the relief of digestive symptoms including burning sensation and dyspepsia.</p> <p>Indication 2</p> <p>Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>a) Comminuted herbal substance</p> <p>Herbal tea:</p> <p>1.5 - 2 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion 2 to 4 times daily</p> <p>or</p> <p>1.5 - 2 g of comminuted herbal substance in 150 ml of water as a decoction 2 to 4 times daily.</p> <p>Take one cup after meals.</p> <p>b) Soft extract (DER 1:0.4-0.5)</p> <p>32 mg 2-3 times daily for oral use. Not more than 160 mg (32 mg 5 times) daily.</p> <p>Indication 2</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>a) Comminuted herbal substance</p>

	<p>1.5 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion 2 times daily</p> <p>or</p> <p>1.5 g of comminuted herbal substance in 150 ml of water as a decoction 2 times daily.</p> <p>c) Soft extract (DER 3:1)</p> <p>1.2-1.5 g 3-4 times daily.</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>Indication 1</p> <p>Not to be used for more than 4 weeks.</p> <p>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.</p> <p>Indication 2</p> <p>If the symptoms persist longer than 1 week 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>
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4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

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 has not been established due to lack of adequate data.</p> <p>Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as hypokalemia, hypertension, cardiac rhythm disorders.</p>

Well-established use	Traditional use
	<p>Liquorice medication should be used with caution in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of liquorice.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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

Well-established use	Traditional use
	<p>Liquorice root may counteract antihypertensive action of prescribed medications.</p> <p>Not to be used concomitantly with thiazide diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Well-established use	Traditional use
	<p>Hypokalaemia, hypertension, cardiac rhythm disorders, hypertension encephalopathy may</p>

Well-established use	Traditional use
	<p>occur. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	<p>Cases of overdose have been reported with prolonged use and/or intake of high amount of liquorice, with symptoms similar than those reported in section 4.8 'Undesirable effects'.</p>

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data³

Well-established use	Traditional use
	<p>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.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

³ Where herbal preparations from *Liquiritiae radix* are used, the total exposure to glycyrrhizic acid should be considered from a safety standpoint.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 July 2011