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

Final

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

3. Pharmaceutical form

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

4.2. Posology and method of administration[3]

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

[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).

	Indication 2 *Adults and elderly* Single dose a) Comminuted herbal substance 1.5 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion 2 times daily or 1.5 g of comminuted herbal substance in 150 ml of water as a decoction 2 times daily. c) Soft extract (DER 3:1) 1.2-1.5 g 3-4 times daily. d) doses of dry extracts corresponding to c) The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1 Not to be used for more than 4 weeks. 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. Indication 2 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. **Method of administration** Oral use.

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
	Indication 1 and 2

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. Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders. Liquorice medication is not recommended to be used in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of liquorice. Concomitant use with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance is not recommended (see section 4.5). Indication 2 If dyspnoea, fever or purulent sputum occurs, 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
	Liquorice root may counteract antihypertensive action of prescribed medications. Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (see section with 4.4).

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Studies in animals have shown reproductive

	toxicity (see section 5.3 'Preclinical safety data'). 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
	If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	Cases of overdose have been reported with prolonged use (more than 4 weeks) and/or intake of high amount of liquorice, with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.

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. A study has shown that 18β-glycyrrhetinic acid[4] crosses through the placental barrier and can be detected in the rat foetuses. Following feeding of dams with 100 mg 18β-glycyrrhetinic acid/kg/day commencing on the 13th day of gestation, on the 17th, 19th and 21st days of gestation the maternal plasma 18β-glycyrrhetinic acid concentrations were approximately 100 µg/ml, whereas the foetal concentrations were 5, 18 and 32 µ/ml, respectively. In developmental toxicity studies, glycyrrhizin (ammonium salt) exhibited some embryotoxicity to the developing rat foetus, but the foetal effects were considered as minor. These effects were shown at the dose of 100 and 250 mg/kg of ammonium glycyrrhizin from 7th to 20th day of pregnancy (soft-tissue abnormalities, mostly renal, and external haemorrhages) and at the dose of 1000 mg/kg of 18β-glycyrrhetinic acid from the 13th day of gestation (significant reduction in lamellar body content of lungs and reduced number alveolar lamellar body and surfactant clusters, but no apparent increase in malformation or foetal death rate). Another study suggested that 100 mg/kg of liquorice extract repeated for 7 days may also aggravate body weight loss and malformations of foetuses, induced by intrauterine exposure to cyclophosphamide.

[4] Where herbal preparations from Liquiritiae radix are used, the total exposure to 18β-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

22 May 2012