



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Glycyrrhiza glabra* L.; *Glycyrrhiza inflata* Bat.; *Glycyrrhiza uralensis* Fisch., radix

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2010 January 2011 March 2011 May 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	July 2011
End of consultation	15 November 2011
Rediscussion in MLWP	November 2011 January 2012 March 2012
Adoption by HMPC Monograph (EMA/HMPC/571119/2010) Assessment Report (EMA/HMPC/571122/2010) List of References (EMA/HMPC/571121/2010) Overview of Comments received during the public consultation (EMA/HMPC/48932/2012) HMPC Opinion (EMA/HMPC/332117/2012)	22 May 2012
First revision	
Discussion in HMPC	March 2024 July 2024 November 2024 March 2025 May 2025 July 2025
Adopted by HMPC for release for consultation	09 July 2025
Start of public consultation	01 August 2025



End of consultation (deadline for comments ¹)	31 October 2025
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Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; traditional use; <i>Glycyrrhiza glabra</i> L. and/or <i>Glycyrrhiza inflata</i> Bat. and/or <i>Glycyrrhiza uralensis</i> Fisch., radix; Liquiritiae radix; liquorice root
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BG (bulgarski): Сладник	LT (lietuvių kalba): Saldymedžių šaknys
CS (čeština): lékořicový kořen	LV (latviešu valoda): Lakricu sakne
DA (dansk): Lakridsrod	MT (Malti): għerq ta' għud is-sus
DE (Deutsch): Süßholzwurzel	NL (Nederlands): Zoethoutwortel
EL (elliniká): γλυκύριζα ρίζα	PL (polski): Korzeń lukrecji
EN (English): Liquorice root	PT (português): alcaçuz, raiz
ES (español): regaliz, raíz de	RO (română): rădăcină de lemn dulce
ET (eesti keel): magusjuurejuur	SK (slovenčina): koreň sladkovky
FI (suomi): lakritsi, juuri	SL (slovenščina): korenina golostebelnega sladkega korena
FR (français): réglisse (racine de)	SV (svenska): lakrits rot
HR (hrvatski): sladićev korijen	IS (íslenska):
HU (magyar): édesgyökér	NO (norsk): lakrisrot
IT (italiano): Liquirizia, radice	

¹ No comments were received during the period of public consultation. Therefore, the final monograph is published together with the final assessment report and list of references, without an 'overview of comments received during the public consultation'.

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1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{2, 3}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Glycyrrhiza glabra</i> L.; <i>Glycyrrhiza inflata</i> Bat.; <i>Glycyrrhiza uralensis</i> 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

3. Pharmaceutical form

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

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

³ The material complies with the Ph. Eur. monograph (ref.: 01/2012:0277).

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 administration⁴

Well-established use	Traditional use
	Posology Indication 1) <i>Adults and elderly</i> a) Comminuted herbal substance Herbal tea: 1.5 - 2 g of comminuted herbal substance in 150 ml of boiling water as an herbal infusion or decoction, 2 to 4 times daily. Take one cup after meals. Daily dose: 3 – 8 g. b) Soft extract (DER 1:0.4-0.5) Single dose: 32 mg, 2-3 times daily. Daily dose: 64 – 96 mg (max 160 mg daily). Indication 2) <i>Adults and elderly</i> a) Comminuted herbal substance Herbal tea: 1.5 g – 4.5 g of comminuted herbal substance in 150 ml of boiling water as an herbal infusion or decoction, 2-3 times daily.

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
	Daily dose: 3 – 13.5 g. c) Soft extract (DER 3:1) Single dose: 1.2-1.5 g, 3-4 times daily. Daily dose: 3.6 – 6 g. 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
	Indications 1) and 2) 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

Well-established use	Traditional use
	take other liquorice containing products as serious adverse events may occur such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders. Liquorice medication is not recommended in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalaemia, 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). Caution is advised when liquorice is taken concomitantly with drugs known to be substrate of CYP3A4 (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). Liquorice root preparations might affect the activity of CYP3A4. Clinical studies have shown that the oral intake of 300 mg/day of glycyrrhizin for 14 days can modestly decrease the systemic exposure to drugs metabolised by CYP 3A4 enzymes such as midazolam and omeprazole. Caution is advised in case of concomitant use of all drug substances the metabolism of which is influenced by CYP3A4.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	There are limited data from use in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data'). The use is not recommended during pregnancy and in women of childbearing potential not using contraception. Glycyrrhizin is detectable in the breastmilk of some women taking liquorice, but studies measuring glycyrrhetic acid have not been performed. The effect of liquorice root or its constituents on newborns/infants is unknown. The use during breast-feeding is not recommended. No adequate 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, and hypertensive encephalopathy.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	No information required.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	No information required.

5.3. Preclinical safety data⁵

Well-established use	Traditional use
	A study has shown that 18β-glycyrrhetic acid crosses through the placental barrier and can be detected in the rat fetuses. In developmental toxicity studies, glycyrrhizin (as ammonium salt or as free acid) exhibited minor embryotoxicity to the developing rat foetus mainly in kidneys and lungs, at doses from 239 up to 1000 mg/kg starting from 7th day of pregnancy. Another two studies 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. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

⁵ Where herbal preparations from *Liquiritiae radix* are used, the total exposure to glycyrrhizin and 18 β -glycyrrhizic acid should be considered from a safety standpoint.