



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

09 July 2025  
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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

Draft – Revision 1

|  |   |
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| <b>Initial assessment</b>  |   |
| Discussion in Working Party on European Union monographs and European Union list (MLWP)  | September 2010<br>January 2011<br>March 2011<br>May 2011                        |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation  | July 2011   |
| End of consultation  | 15 November 2011  |
| Re-discussion in MLWP  | November 2011<br>January 2012<br>March 2012                                     |
| Adoption by HMPC<br>Monograph (EMA/HMPC/571119/2010)<br>Assessment Report (EMA/HMPC/571122/2010)<br>List of References (EMA/HMPC/571121/2010)<br>Overview of Comments received during the public consultation (EMA/HMPC/48932/2012)<br>HMPC Opinion (EMA/HMPC/332117/2012) | 22 May 2012   |
| <b>First revision</b>  |   |
| Discussion in HMPC   | March 2024<br>July 2024<br>November 2024<br>March 2025<br>May 2025<br>July 2025 |
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| End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a> . | 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.; <i>Glycyrrhiza inflata</i> Bat.; <i>Glycyrrhiza uralensis</i> Fisch., radix; Liquiritiae radix; Liquorice root |
|----------|---|

|                                     |   |
|-------------------------------------|---|
| 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): γλυκύρριζας ρίζα     | PL (polski): Korzeń lukrecji                              |
| EN (English): Liquorice root        | PT (português): alcaçuz, raiz                             |
| ES (español): regaliz, raíz de      | RO (română): rădăcină de lemn dulce                       |
| EE (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   |   |

European Union herbal monograph on *Glycyrrhiza glabra* L.; *Glycyrrhiza inflata* Bat.; *Glycyrrhiza uralensis* Fisch., 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<br><i>Glycyrrhiza glabra</i> L.; <i>Glycyrrhiza inflata</i> Bat.; <i>Glycyrrhiza uralensis</i> Fisch., radix (Liquorice root)<br><br>i) Herbal substance<br><br>Not applicable.<br><br>ii) Herbal preparations<br><br>a) Comminuted herbal substance<br><br>b) Soft extract (DER 1:0.4-0.5), extraction solvent water<br><br>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.<br><br>Herbal preparations in liquid dosage forms for oral use.<br><br>The pharmaceutical form should be described by the European Pharmacopoeia full standard term. |

<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.: 01/2012:0277).

## 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<sup>3</sup>

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

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>Herbal tea: 1.5 g – 4.5 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion or decoction, 2-3 times daily.</p> <p>Daily dose: 3 – 13.5 g</p> <p>c) Soft extract (DER 3:1)</p> <p>Single dose: 1.2-1.5 g, 3-4 times daily.</p> <p>Daily dose: 3.6 – 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>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><b>Method of administration</b></p> <p>Oral use.</p> |

#### 4.3. Contraindications

| Well-established use | Traditional use                            |
|----------------------|--|
|                      | Hypersensitivity to the active substances. |

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

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> |

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as water retention, hypokalaemia, hypertension, and cardiac rhythm disorders.</p> <p>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.</p> <p>Concomitant use with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance is not recommended (see section 4.5).</p> <p>Caution is advised when liquorice is taken concomitantly with drugs known to be substrate of CYP3A4 (see section 4.5).</p> <p><b>Indication 2)</b></p> <p>If dyspnoea, fever or purulent sputum occurs, 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 diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (see section with 4.4).</p> <p>Liquorice root preparations might induce the activity of CYP3A4. Clinical studies have shown that the oral intake of 300 mg/day of glycyrrhizin for 14 days can significantly decrease the systemic exposure to drugs metabolised by CYP</p> |

| Well-established use | Traditional use   |
|----------------------|---|
|                      | 3A4 enzymes such as midazolam and omeprazole. Special care should be taken in case of concomitant use of all drug substances the metabolism of which is influenced by CYP3A4, because a reduction of plasma concentrations is possible. |

#### 4.6. Fertility, pregnancy and lactation

| Well-established use | Traditional use   |
|----------------------|---|
|                      | <p>There are limited data from use in pregnant women.</p> <p>Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').</p> <p>The use is not recommended during pregnancy and in women of childbearing potential not using contraception.</p> <p>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.</p> <p>No adequate fertility data available.</p> |

#### 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 data<sup>4</sup>

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>A study has shown that 18<math>\beta</math>-glycyrrhetic acid crosses through the placental barrier and can be detected in the rat fetuses.</p> <p>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 7<sup>th</sup> day of pregnancy.</p> <p>Another two studies suggested that 100 mg/kg of liquorice extract repeated for 7 days may also aggravate body weight loss and malformations of fetuses, induced by intrauterine exposure to cyclophosphamide.</p> |

<sup>4</sup> Where herbal preparations from *Liquiritiae radix* are used, the total exposure to glycyrrhizin and 18 $\beta$ -glycyrrhizic acid should be considered from a safety standpoint.



| Well-established use | Traditional use  |
|----------------------|--|
|                      | 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

09 July 2025