8 July 2020
EMA/HMPC/554043/2018
Committee on Herbal Medicinal Products (HMPC)

# European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba

Final

| **Initial assessment** | |
|---|---|
| Discussion in Working Party on European Union monographs and European Union list (MLWP) and Committee on Herbal Medicinal Products (HMPC) | September 2018<br>May 2019<br>July 2019<br>November 2019 |
| Adopted by HMPC for release for consultation | 20 November 2019 |
| Start of public consultation | 19 December 2020 |
| End of consultation. | 15 March 2020 |
| Re-discussion in HMPC/MLWP | May 2020<br>July 2020 |
| Adoption by HMPC | 8 July 2020 |

| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba; Herniariae herba; rupturewort |
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| | |
|---|---|
| BG (bulgarski): Изсипливче, стрък<br>CS (čeština): průtržníková nať<br>DA (dansk): Brudurt<br>DE (Deutsch): Bruchkraut<br>EL (elliniká): Ερνιάριας πόα<br>EN (English): rupturewort<br>ES (español): Herniaria, parte aérea de<br>ET (eesti keel):<br>FI (suomi): tyräruoho, verso<br>FR (français): herniaire<br>HR (hrvatski): kilavičina zelen<br>HU (magyar): porcikafű<br>IT (italiano): Erniaria, parti aeree | LT (lietuvių kalba): Skleistenių žolė<br>LV (latviešu valoda): trūkumzālītes laksti<br>MT (Malti): Ħaxixa tal-Ħerniarja<br>NL (Nederlands): Breukkruid, kruid<br>PL (polski): ziele połonicznika<br>PT (português): Herniaria, partes aéreas<br>RO (română): iarbă de feciorică<br>SK (slovenčina): vňať prietržníka<br>SL (slovenščina): zel kilavca<br>SV (svenska): knytling, ört<br>IS (íslenska):<br>NO (norsk): |

# European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba

## 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<br><br>*Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba (rupturewort) or a mixture of them<br><br>i) Herbal substance<br><br>Not applicable<br><br>ii) Herbal preparations<br><br>Comminuted herbal substance |

## 3. Pharmaceutical form

| Well-established use | Traditional use |
|---|---|
| | Comminuted herbal substance as herbal tea for oral use.<br><br>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 to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.<br><br>The product is a traditional herbal medicinal |

[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 Monograph in the Austrian Pharmacopoeia (monograph ÖAB 2010/056)

| Well-established use | Traditional use |
|---|---|
| | product for use in the specified indication exclusively based upon long-standing use. |

## *4.2. Posology and method of administration*[3]

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br><br>*Adults and Elderly*<br>Herbal tea: 1.5-3 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml water as decoction 3-5 times daily.<br><br>Maximum daily dose: 10 g.<br><br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br><br>**Duration of use**<br><br>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.<br><br>**Method of administration**<br><br>Oral use |

## *4.3. Contraindications*

| Well-established use | Traditional use |
|---|---|
| | Hypersensitivity to the active substance.<br><br>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease). |

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

| 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. |

[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).

| Well-established use | Traditional use |
|---|---|
| | To ensure an increase of the amount of urine, adequate fluid intake is required during the treatment.<br><br>If urinary tract complaints worsen and symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of medicinal product, 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 |
|---|---|
| | 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.<br><br>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 |
|---|---|
| | None known<br><br>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. |

## *5.2. Pharmacokinetic properties*

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

## *5.3. Preclinical safety data*

| Well-established use | Traditional use |
|---|---|
| | Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.<br>Adequate tests on genotoxicity have not been performed.<br>Tests on reproductive toxicity and carcinogenicity have not been performed. |

# 6. Pharmaceutical particulars

| Well-established use | Traditional use |
|---|---|
| | Not applicable |

# 7. Date of compilation/last revision

8 July 2020