



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/39453/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Sideritis scardica* Griseb.; *Sideritis clandestina* (Bory & Chaub.) Hayek; *Sideritis raeseri* Boiss. & Heldr.; *Sideritis syriaca* L., herba Final

Discussion in Working Party on European Union monographs and list (MLWP)	September 2014 January 2015 March 2015 May 2015
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	07 July 2015
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Sideritis scardica</i> Griseb.; <i>Sideritis clandestina</i> (Bory & Chaub.) Hayek; <i>Sideritis raeseri</i> Boiss. & Heldr.; <i>Sideritis syriaca</i> L., herba; Sideritis herba; ironwort
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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'.



BG (bulgarski): Мурсалски чай, стрък	LT (lietuvių kalba): Timsrų žolė
CS (čeština): nař hojnřku	LV (latviešu valoda): Siderřtu laksts
DA (dansk): Kortkroneurt	MT (Malti): ħaxixa tas-Sideritis
DE (Deutsch): Berufskraut	NL (Nederlands): (Griekse) bergthee, kruid
EL (elliniká): Πόα σιδηρίτου	PL (polski): Ziele gojnika
EN (English): ironwort	PT (português): Siderite, partes aéreas
ES (español): Siderita, partes aéreas de	RO (română): iarba de ceaiul muntelui cretan
ET (eesti keel): haavarohuürt	SK (slovenčina): Vňar řanhoja
FI (suomi): raudakki, verso	SL (slovenščina): zel sklepnjaka
FR (français): Crapaudine (parties aériennes de)	SV (svenska): Sårmynta, ört
HR (hrvatski): očistova zelen	IS (islenska):
HU (magyar): sármányvirág virágos hajtása	NO (norsk): Gresk fjellte
IT (italiano): Stregonia parti aeree fiorite	

European Union herbal monograph on *Sideritis scardica* Griseb.; *Sideritis clandestina* (Bory & Chaub.) Hayek; *Sideritis raeseri* Boiss. & Heldr.; *Sideritis syriaca* L., herba

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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Sideritis scardica</i> Griseb.; <i>Sideritis clandestina</i> (Bory & Chaub.) Hayek, <i>Sideritis raeseri</i> Boiss. & Heldr.; <i>Sideritis syriaca</i> L., herba (ironwort)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

3. Pharmaceutical form

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for the</p>

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

³ Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State

Well-established use	Traditional use
	<p>relief of cough associated with cold.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product used for the relief of mild gastrointestinal discomfort.</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 administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Indication 1) and 2)</p> <p>Single dose:</p> <p>Herbal tea: 2-4 g of the comminuted herbal substance in 150-200 ml of water as a herbal infusion 2-3 times daily</p> <p>Daily dose up to 12 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>Duration of use</p> <p>Indication 1)</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>Indication 2)</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>Method of administration</p> <p>Oral use</p>

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).

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family.

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. If the symptoms worsen during the use of the 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. 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 If adverse reactions occur, a doctor or a qualified

Well-established use	Traditional use
	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 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
	<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>Four <i>Sideritis scardica</i> dry extracts of different polarity (water, 20% and 50% V/V ethanol, and n-heptane) were tested (AMES-test in <i>Salmonella typhimurium</i> strains TA 98, TA 100, TA 1535, TA 1537 and TA 102 with and without metabolic activation). No signs of genotoxicity and mutagenicity were observed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

2 February 2016