

**COMMISSION IMPLEMENTING DECISION (EU) 2018/134****of 24 January 2018****amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products***(notified under document C(2018) 218)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <sup>(1)</sup>, and in particular Article 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 2 February 2016 by the Committee for Herbal Medicinal Products

Whereas:

- (1) *Sideritis scardica* Griseb., herba can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.
- (2) It is therefore appropriate to include *Sideritis scardica* Griseb., herba in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC <sup>(2)</sup>.
- (3) Decision 2008/911/EC should therefore be amended accordingly.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

*Article 1*

Annexes I and II to Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 24 January 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(2)</sup> Commission Decision 2008/911/EC of 21 November 2008 establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42).

## ANNEX

Decision 2008/911/EC is amended as follows:

(1) In Annex I, the following substance is inserted after *Pimpinella anisum* L:

‘*Sideritis scardica* Griseb., herba.’;

(2) In Annex II, the following is inserted after the COMMUNITY LIST ENTRY on *Pimpinella anisum* L:

‘UNION LIST ENTRY ON *SIDERITIS SCARDIA* GRISEB., HERBA

### Scientific name of the plant

*Sideritis scardica* Griseb.

### Botanical family

Lamiaceae (Labiatae)

### Herbal substance

Ironwort (*Sideritis herba*)

### Common name in all EU official languages of herbal preparation

BG (bългарski): Мурсалски чай, стрък	LT (lietuvių kalba): Timsrų žolė
CS (čeština): nať hojníku	LV (latviešu valoda): Siderītu laksts
DA (dansk): Kortkroneurt	MT (Malti): ħaxixa tas-Sideritis
DE (Deutsch): Balkan-Gliedkraut	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): haavarohtuürt	SK (slovenčina): Vňat' ráňhoja
FI (suomi): raudakki, verso	SL (slovenščina): zel sklepnjaka
FR (français): Crapaudine (parties aériennes de)	SV (svenska): Sårmynta, ört
HR (hrvatska): očistova zelen	IS (íslenska):
HU (magyar): sármányvirág virágos hajtása	NO (norsk): Gresk fjellte
IT (italiano): Stregonia parti aeree fiorite	

### Herbal preparations

Comminuted herbal substance

### European Pharmacopoeia monograph reference

Not applicable

### Indications

Indication (1)

Traditional herbal medicinal product used for the relief of cough associated with cold.

Indication (2)

Traditional herbal medicinal product used for the relief of mild gastrointestinal discomfort.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

**Type of tradition**

European

**Specified strength**

Please see "Specified posology".

**Specified posology**

*Adults and elderly*

Indication (1) and (2)

Single dose: Herbal tea: 2-4 g of the comminuted herbal substance in 150-200 ml of water as a herbal infusion 2-3 times daily

Daily dose: up to 12 g

The use in children and adolescents under 18 years of age is not recommended (see section "Special warnings and precautions for use")

**Route of administration**

Oral use

**Duration of use or any restrictions on the duration of use**

Indication (1)

If symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Indication (2)

If symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

**Any other information necessary for the safe use***Contraindications*

Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family.

*Special warnings and precautions for 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.

*Interactions with other medicinal products and other forms of interaction*

None reported

*Fertility, pregnancy and lactation*

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, use during pregnancy and lactation is not recommended.

No fertility data available.

*Effects on ability to drive and use machines*

No studies on the effect on the ability to drive and use machines have been performed.

*Undesirable effects*

None known

If adverse reactions occur, a doctor or qualified health care practitioner should be consulted.

*Overdose*

No case of overdose has been reported.

*Pharmaceutical particulars (if necessary)*

Not applicable

*Pharmacological effects or efficacy plausible on the basis of long-standing use and experience (if necessary for the safe use of the product)*

Not applicable.'

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