COMMISSION IMPLEMENTING DECISION (EU) 2018/133

of 24 January 2018

amending Decision 2008/911/EC shing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2018) 213)

(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 ([1]), 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) *Valeriana officinalis* L. 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 *Valeriana officinalis* L. in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ([2]).

(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

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Commission Decision 2008/911/EC of 21 November 2008 establishing of 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 *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum:

'*Valeriana officinalis* L.';

(2) in Annex II, the following is inserted after the COMMUNITY LIST ENTRY on *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum:

'UNION LIST ENTRY ON *VALERIANA OFFICINALIS* L.

Scientific name of the plant

Valeriana officinalis L.

Botanical family

Valerianaceae

Common name in all EU official languages of herbal preparation

BG (bălgarski): Валериана, корен
CS (čeština): kozlíkový kořen
DA (dansk): Baldrianrod
DE (Deutsch): Baldrianwurzel
EL (elliniká): Ρίζα βαλεριανής
EN (English): Valerian root
ES (español): Valeriana, raíz de
ET (eesti keel): palderjanijuur
FI (suomi): rohtovirmajuuri, juuri
FR (français): Valériane (racine de)
HR (hrvatska): odoljenov korijen
HU (magyar): Macskagyökér
IT (italiano): Valeriana radice
LT (lietuvių kalba): Valerijonų šaknys
LV (latviešu valoda): Baldriāna saknes
MT (Malti): Għerq tal-Valerjana
NL (Nederlands): Valeriaanwortel
PL (polski): Korzeń kozłka
PT (português): Valeriana, raiz
RO (română): rădăcină de valeriană
SK (slovenčina): Koreň valeriány
SL (slovenščina): korenina zdravilne špajke
SV (svenska): Vänderot, rot
IS (íslenska):
NO (norsk): Valerianarot

Herbal preparation(s)

(a) Comminuted herbal substance
(b) Powdered herbal substance
(c) Expressed juice from fresh root (1:0,60-0,85)
(d) Dry extract (DER 4-6:1), extraction solvent: water
(e) Liquid extract (DER 1:4-6), extraction solvent: water
(f) Dry extract (DER 4-7:1), extraction solvent: methanol 45 % (V/V)
(g) Dry extract (DER 5,3-6,6:1), extraction solvent: methanol 45 % (m/m)
(h) Liquid extract (DER 1:7-9), extraction solvent: sweet wine
(i) Liquid extract (DER 1:1), extraction solvent: ethanol 60 % (V/V)
(j) Tincture (ratio of herbal substance to extraction solvent 1:8), extraction solvent: ethanol 60 % (V/V)
(k) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent: ethanol 56 %
(l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70 % (V/V)
(m) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 60-80 % (V/V)
(n) Dry extract (DER 5,5-7,4:1), extraction solvent: ethanol 85 % (m/m)

European Pharmacopoeia monograph reference

04:2017:0453

Indications

Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep.

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

Type of tradition

European.

Specified strength

Please see 'Specified posology'.

Specified posology

Adolescents, adults and elderly

Oral use

(a) single dose: 0,3-3 g

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

Herbal tea: 0,3-3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion

(b) single dose: 0,3-2,0 g

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(c) single dose: 10 ml

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(d) single dose: 420 mg

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(e) single dose: 20 ml

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime.

(f) single dose: 144-288 mg

For relief of mild symptoms of mental stress up to 4 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(g) single dose: 450 mg

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(h) single dose: 10 ml, up to 3 times daily

(i) single dose: 0,3-1,0 ml, up to 3 times daily

(j) single dose: 4-8 ml, up to 3 times daily

(k) single dose: 0,84 ml

For relief of mild symptoms of mental stress 3-5 times daily.

To aid sleep, a single dose half an hour before bedtime.

(l) single dose: 1,5 ml (mental stress), 3 ml (to aid sleep)

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half an hour before bedtime.

(m) single dose: 10 ml, up to 3 times daily

(n) single dose: 322 mg, up to 3 times daily

Use as bath additive

single dose: 100 g for a full bath, up to 1 bath daily

Route of administration

Oral use

Use as bath additive. Temperature: 34-37 °C, duration of bath 10-20 minutes.

Duration of use or any restrictions on the duration of use

If symptoms persist 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.

Use as bath additive

Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.

Special warnings and precautions for use

The use in children under 12 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.

For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

Undesirable effects

Oral use

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian root preparations. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Use as bath additive

None known

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

Overdose

Oral use

Valerian root at a dose of approximately 20 g caused symptoms, such as fatigue, abdominal cramp, chest tightness, light-headedness, hand tremor and mydriasis, which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

Use as bath additive

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.'