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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Fucus vesiculosus* L., thallus

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2012 September 2012 November 12 January 2013 March 2013
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BG (bulgarski): Фукус везикулозус	LT (lietuvių kalba): Pūslėtųjų guveinių gniužulai
CS (čeština): chaluha	LV (latviešu valoda): Fuka laponis
DA (dansk): Blæretang	MT (Malti): Fukus
DE (Deutsch): Blasentang	NL (Nederlands): blaaswier
EL (elliniká): Φύκος το κυστώδες	PL (polski): morszczyn pęcherzykowaty
EN (English): bladderwrack	PT (português): bodelha
ES (español): fucus	RO (română): Fucus
ET (eesti keel): põisadru	SK (slovenčina): chaluha
FI (suomi): rakkolevä	SL (slovenščina): zel mehurjastega bračiča
FR (français): Fucus (thalle de)	SV (svenska): blåstång
HR (hrvatski): mjehurasti bračić	*IS (íslenska)*:
HU (magyar): barnamoszattelep	*NO (norsk):* blæretang
IT (italiano): Quercia marina tallo	

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Community herbal monograph on *Fucus vesiculosus* L., thallus

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 as amended *Fucus vesiculosus* L., thallus (bladderwrack) i) Herbal substance Not applicable. ii) Herbal preparations Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid dosage forms for oral use. 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 used as an adjuvant to reduced calorie diet to help weight loss in overweight adults, after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in the specified indication

[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 Ph. Eur. monograph (ref.: 01/2008:1426, corrected 6.0).

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and Elderly* Single dose Powdered herbal substance: 130 mg, twice daily with a glass of water, 2 hours before meals. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If patients taking *Fucus vesiculosus* have been unable to lose weight after 10 weeks, they should consult a doctor or a qualified health care practitioner. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice. Other herbal preparations containing *Fucus vesiculosus*, preparations containing iodine or medicines for the thyroid gland should not be taken concomitantly.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	**Traditional use**
	One case report of hyperthyroidism was published in a patient diagnosed with bipolar disorder and under treatment with lithium.

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. There are no or limited data from use during No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	**Traditional use**
	Not relevant.

4.8. Undesirable effects

Well-established use	**Traditional use**
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	**Traditional use**
	The daily intake of 700 or 1,400 mg (n=3) for several weeks resulted in an increased inter menstrual period. Intake of higher dosages than recommended can change the TSH levels. (see also section 6 pharmaceutical particulars) Exceeding doses may cause aggravation of acne, heart palpitation, increased heart rate, trembling, changes in blood pressure, and increased basal metabolism.

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**
	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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	The upper daily limit of 400 µg total iodine per day following intake of *Fucus vesiculosus* containing medicinal products should not be exceeded. According to the European Pharmacopoeia monograph, the iodine content of *Fucus vesiculosus* powder should contain a minimum of 0.03% and a maximum of 0.2% of iodine. Batches of herbal preparations should be mixed in order to respect the specified upper daily limit of iodine when taking the therapeutic doses mentioned under section 4.2.

7. Date of compilation / last revision

6 May 2014