



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/283231/2014  
EMA/HMPC/M/H/152  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a Community herbal monograph on *Fucus vesiculosus* L., thallus

### Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 24 out of 28 votes a Community herbal monograph on *Fucus vesiculosus* L., thallus which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The Community herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 6 May 2014

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



## **Annex I: Community herbal monograph (EMA/HMPC/313674/2012)**

## **Appendix I: Assessment report (EMA/HMPC/313675/2012)**

## Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Fucus vesiculosus* L., thallus for the reason presented below:

The maximum daily intake of iodine might be up to 400 µg/day. This is within and/or above the authorised therapeutic intake of iodine for indications connected to "prophylaxis and treatment of struma", for which contraindications (e.g. hyperthyreosis, adenoma of the thyroidsoides) and undesirable effects are known. Therefore a traditional use of such high dosages of iodine cannot be supported.

Jacqueline Wiesner, HMPC member from Germany

London, 6 May 2014

One member of the HMPC did not agree with the HMPC's opinion on *Fucus vesiculosus* L., thallus for the reason presented below:

Due to the thyroid risk posed by overdose of iodine.

Eeva Sofia Leinonen, HMPC member from Finland

London, 6 May 2014

One member of the HMPC did not agree with the HMPC's opinion on *Fucus vesiculosus* L., thallus for the reason presented below:

- The proposed use cannot be regarded as a medical indication, especially used for a traditional herbal medicinal product.
- Safety concerns remain with respect to the iodine intake, compared to the maximum daily intake recommendations established.
- Concerns regarding hormonal effects are not complying with safety requirements for traditional herbal medicinal products.

Emiel van Galen, HMPC member from The Netherlands

London, 6 May 2014

One member of the HMPC did not agree with the HMPC's opinion on *Fucus vesiculosus* L., thallus for the reason presented below:

The maximum daily intake of iodine might be up to 400 µg/day. This is within and/or above the authorised therapeutic intake of iodine for indications connected to "prophylaxis and treatment of struma", for which contraindications (e.g. hyperthyreosis, adenoma of the thyroidsoides) and undesirable effects are known. Therefore a traditional use of such high dosages of iodine cannot be supported.

Jacqueline Wiesner, HMPC member from Germany

London, 6 May 2014