

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)**

***FOENICULUM VULGARE* MILLER SUBSP. *VULGARE*  
VAR. *DULCE* (MILLER) THELLUNG, FRUCTUS**

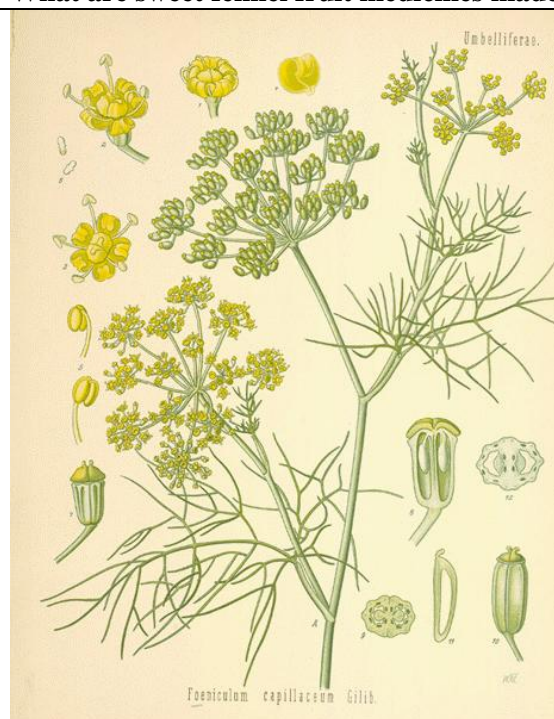
**FENNEL FRUIT, SWEET**

**HMPC Assessment Report Summary for the Public**

*This document is a summary of the **assessment report** adopted by the Committee on Herbal Medicinal Products (HMPC) that describes the data available on the medicinal use of a herbal substance and the conclusions after evaluating these data.*

*If you want more information on the HMPC conclusions, read the **Community list entry** on this herbal medicine. Community list entries are authorised by the European Commission further to the scientific opinion of the HMPC and describe the herbal medicines, including their content, how they are used, what they are used for, how they work and how they can be used safely.*

**What are sweet fennel fruit medicines made of?**



Sweet fennel fruit medicines contain the fruit of the sweet fennel plant. The botanical Latin name of the plant is *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung.

Sweet fennel is a plant that grows wild in most parts of temperate Europe, but is generally considered indigenous to the shores of the Mediterranean from where it spreads eastwards to India. The plant is cultivated to obtain the fruits (also commonly called fennel seeds) for medicinal use (herbal substance).

**IMPORTANT NOTE:** The image is provided to give additional information on the source of the herbal substance/preparation. This image is not intended to encourage collection from the wild.

Sweet fennel fruit medicines are available in various forms to be taken by mouth, such as herbal tea, tablets, capsules. They are made from the dried fruit comminuted, crushed or powdered.

Preparations made from sweet fennel fruit can also be found in combination with other herbal substances. These combination medicines will be assessed separately by the HMPC.

#### **What are sweet fennel fruit medicines used for?**

Sweet fennel fruit medicines are traditionally used for:

- symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- symptomatic treatment of minor spasm (cramps) associated with menstrual periods.
- as an expectorant (helps to expel mucus) in cough associated with colds.

The HMPC came to these conclusions after assessment of the bibliographic data available on sweet fennel fruit preparations. The justification for the use of these preparations is found in their traditional use as herbal medicines.

Many traditional herbal medicines have not been fully investigated with current scientific methods. The EU pharmaceutical legislation provides an opportunity for traditional herbal medicines to be officially registered, based on their traditional use, if they can be used safely without the support from a medical doctor for diagnosis, treatment and follow-up. This traditional use must cover a period of at least 30 years with 15 years of this use within the Community.

#### **How are sweet fennel fruit medicines used?**

Sweet fennel fruit medicines can be used from the age of 4 years. Sweet fennel fruit medicines are not recommended for use in children under 4 years of age because there is not enough information on their safe use in this group.

The dose of sweet fennel fruit medicines and how often they are used depends on what they are being used for and the formulation of the medicine being used. Detailed instructions can be found in the package leaflet that comes with each medicinal product.

They are generally taken three to four times a day and they should be taken for not more than 1-2 weeks. For further information, see section 'Specified posology of the Community list entry on sweet fennel fruit.'

#### **How do sweet fennel fruit medicines work?**

Many components have been identified in preparations containing sweet fennel fruit and it is not possible to define precisely the action of each component.

Clinical trials on sweet fennel fruit medicines are limited, but pharmacological data support the plausibility of the traditional medicinal use.

Studies on isolated components of these medicines could not fully explain the activity of the medicines, so it is thought that several components in sweet fennel fruit preparations work together to bring about their effects.

#### **What studies were conducted with sweet fennel fruit medicines?**

Because sweet fennel fruit has been in use for a long time, the data reviewed by the HMPC included the results of studies from the scientific literature including studies using experimental models.

A relaxing effect on isolated contracted smooth muscles of alcoholic extracts of fennel and fennel essential oil has been reported.

Moreover an anti-inflammatory effect has been reported following oral administration to rats.

It has been observed that a number of compounds detected in fennel fruit inhibit the growth of pathogenic bacteria and fungi. The relaxing and anti-inflammatory effects together with the antimicrobial

action of their constituents may contribute to the traditional use of sweet fennel medicines in the treatment of minor spasmodic gastro-intestinal complaints and in the treatment of cough associated with colds. Furthermore, the secretolytic and expectorant effect of two main components of sweet fennel fruit (anethole and estragole) observed in a study conducted in rabbits, could also support the plausibility of the traditional use of fennel in cough associated with colds.

There are few studies looking at the safety of sweet fennel fruit preparations, but the many years of experience of their use in man indicate that they are sufficiently safe.

The long-standing use over more than 30 years and limited experimental studies make the traditional use in the above-mentioned indications plausible.

#### **What are the risks associated with sweet fennel fruit medicines?**

Sweet fennel fruit medicines are generally well tolerated. The most common side effects with sweet fennel fruit medicines are related to allergic reactions, affecting the skin or the respiratory system. Sweet fennel fruit medicines should not be used in people who may be hypersensitive (allergic) to sweet fennel.

The full list of all side effects reported for a given sweet fennel fruit medicine is found in its package leaflet.

Because there have been no tests looking at the effects of sweet fennel fruit medicines during pregnancy or lactation, they should not be used in women who are pregnant or breast-feeding as a general precaution.

#### **Other information about sweet fennel fruit medicines**

The medicinal use of sweet fennel fruit is part of traditional European Phytotherapy. It is also part of Chinese traditional medicine.

**Important information on the use of a traditional herbal medicine can be found in the package leaflet that comes with each individual product. This information should always be read carefully before using a product.**

Further information on the HMPC assessment on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung is provided in the HMPC Assessment Report, overview of comments received during the public consultation period and other related documents which can be found [here](#).

The Commission decision establishing the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products can be found [here](#).

**This summary was last updated in January 2009.**