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Herbal medicine: summary for the public

Caraway fruit Carum carvi L., fructus

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of caraway fruit. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing caraway fruit.

This summary is not intended to provide practical advice on how to use medicines containing caraway fruit. For practical information about using caraway fruit medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is caraway fruit?

Caraway fruit is the common name for the fruit of the plant *Carum carvi* L. The plant is cultivated or gathered to obtain the fruit for medicinal use.

Herbal medicines containing whole or comminuted (reduced into tiny pieces) caraway fruit are usually available as a herbal tea to be drunk.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, caraway fruit medicines can be used for the relief of problems of the digestive system such as bloating and flatulence.

Caraway fruit medicines should only be used in adults and adolescents over the age of 12 years. If symptoms last longer than two weeks during treatment, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take caraway fruit medicines and who can use them can be found in the package leaflet that comes with the medicine.

What evidence supports the use of caraway fruit medicines?

The HMPC conclusions on the use of caraway fruit medicines for the relief of digestive problems such as bloating and flatulence are based on their 'traditional use' in this condition. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is

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plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

The HMPC noted the lack of clinical studies on the effects of caraway fruit in patients, but took into account the well documented use of this herbal medicine for the above-mentioned use. For further information, see the HMPC assessment report.

What are the risks associated with caraway fruit medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines.

Caraway fruit medicines must not be used in patients who are hypersensitive (allergic) to caraway fruit or other plants of the *Apiaceae (Umbelliferae)* family (fennel, anise, celery, coriander and dill), to mugwort or birch.

Further information on the risks associated with caraway fruit medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>.

How are caraway fruit medicines approved in the EU?

Any applications for the licensing of medicines containing caraway fruit have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of caraway fruit medicines in EU Member States should be obtained from the relevant national authorities.

Other information about caraway fruit medicines

Further information on the HMPC assessment of caraway fruit medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>. For more information about treatment with caraway fruit medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.