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## Herbal medicine: summary for the public

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### Caraway oil

*Carum carvi* L., aetheroleum

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

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

#### **What is caraway oil?**

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

Caraway oil is obtained by a current of steam through the dried fruit. After cooling, the essential oil separates from the water and can be collected.

Herbal medicines containing caraway oil preparations are usually available in liquid forms to be taken by mouth and in semi-solid forms (such as ointments) to be applied to the skin.

#### **What are the HMPC conclusions on its medicinal uses?**

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

While the skin preparations can be used by people of all ages, the medicines to be taken by mouth are not recommended in children and adolescent (under 18 years of age). If symptoms last for more than 2 weeks during the use of caraway oil medicines, the patient should consult a doctor or qualified healthcare practitioner. Detailed instructions on how to take caraway oil 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 oil medicines?

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

At the time of the HMPC assessment, no side effects had been reported with these medicines. Caraway oil medicines must not be used in people who are hypersensitive (allergic) to caraway oil or other plants of the same *Apiaceae (Umbelliferae)* family (e.g. fennel, anise, celery, coriander and dill).

Further information on the risks associated with caraway oil 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: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find medicine/Herbal medicines for human use).

## How are caraway oil medicines approved in the EU?

Any applications for the licensing of medicines containing caraway oil 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 oil medicines in EU Member States should be obtained from the relevant national authorities.

## Other information about caraway oil medicines

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