



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2016
EMA/305345/2016

Herbal medicine: summary for the public

Aniseed

Pimpinella anisum L., fructus

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

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

What is aniseed?

Aniseed is the common name for the fruit of the plant *Pimpinella anisum* L.

The HMPC conclusions only cover the dried herbal substance (dried aniseed) and aniseed preparations which are obtained by drying and comminuting (reducing into tiny pieces) or crushing the fruit.

These aniseed medicines are usually available as herbal tea to be drunk.

These aniseed medicines may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, these aniseed medicines can be used for treating symptoms of mild indigestion complaints including bloating and flatulence. In addition, they can be used as an expectorant (a medicine that helps bring up phlegm) for coughs associated with colds.

Aniseed medicines should only be used in adults and adolescents over the age of 12 years and should not be taken for longer than two weeks. If symptoms last or get worse during the use of the medicine, a doctor or a qualified health care practitioner should be consulted. Detailed instructions on how to take aniseed medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of aniseed medicines?

The HMPC conclusions on the use of these aniseed medicines for indigestion complaints and coughs 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.

In its assessment, the HMPC considered laboratory studies which showed aniseed preparations to have a relaxant effect on muscles of the gut and airways.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with aniseed medicines?

Aniseed medicines must not be used in patients who are allergic to aniseed or to plants of the Apiaceae family (Umbelliferae) (caraway, celery, coriander, dill, fennel) or anethole. Allergic reactions to aniseed that affect the skin or airways may occur.

Further information on the risks associated with these aniseed 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.

How are aniseed medicines approved in the EU?

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

Other information about aniseed medicines

Further information on the HMPC assessment of aniseed 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. For more information about treatment with aniseed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.