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Herbal medicine: summary for the public

Anise oil

Pimpinella anisum L., aetheroleum

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

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

What is anise oil?

Anise oil is the common name for the essential oil obtained from the dry ripe fruits of the plant *Pimpinella anisum* L.

The HMPC conclusions only cover anise oil preparations which are obtained by steam distillation of the dry ripe fruits.

Herbal medicines containing these anise oil preparations are usually available in solid or liquid forms to be taken by mouth.

Anise oil preparations 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 anise oil preparations 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.

Anise oil medicines should only be used in adults 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 healthcare practitioner should be consulted. Detailed instructions on how to take anise 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 anise oil medicines?

The HMPC conclusions on the use of these anise oil 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 studies in laboratory tests which showed anise oil to have a relaxing effect on the muscle 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 anise oil medicines?

Aniseed oil medicines must not be used in children and adolescents under 18 years. They must also 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 oil that affect the skin or airways may occur.

Further information on the risks associated with these anise 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.

How are anise oil medicines approved in the EU?

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

Other information about anise oil medicines

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