

27 March 2018 EMA/268161/2018 Committee on Herbal Medicinal Products (HMPC)

Artichoke leaf

Cynara cardunculus L. (syn. Cynara scolymus L.), folium

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

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

What is artichoke leaf?

Artichoke leaf is the common name for the leaf of the plant Cynara cardunculus L.

The HMPC conclusions only cover artichoke leaf preparations that are obtained by drying and either comminuting (reducing into tiny pieces) or powdering the leaves, or by putting the plant material in a solvent (such as water or ethanol) to dissolve compounds and form a liquid extract. The solvent is then partially or fully evaporated to obtain a soft or dry extract.

Herbal medicines containing these artichoke leaf preparations are usually available as herbal tea to be drunk and in solid or liquid forms to be taken by mouth.

Artichoke leaf 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 their long-standing use, these artichoke leaf preparations can be used for relief of digestive disorders such as indigestion with a sensation of fullness, bloating and flatulence.

Artichoke leaf medicines should only be used in adults and adolescents over the age of 12 years. If symptoms last longer than 2 week whilst taking the medicine, a doctor or qualified healthcare practitioner should be consulted. Detailed instructions on how to take artichoke leaf medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of artichoke leaf medicines?

The HMPC conclusions on the use of these artichoke leaf medicines for relief of digestive disorders 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 also considered clinical studies involving patients with digestive disordes. Results indicated that artichoke leaf may improve symptoms of indigestion. However, firm conclusions could not be drawn due to the poor design of the studies which were small and of short duration. Therefore, the HMPC conclusions on the use of these artichoke leaf medicines are based on their long-standing use.

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

What are the risks associated with artichoke leaf medicines?

Side effects with artichoke leaf medicines include slight diarrhoea with abdominal (belly) spasm, nausea and heartburn. Allergic reactions may also occur. The frequency of these side effects is not known.

Artichoke leaf medicines must not be used in patients with certain disorders of the liver and bile ducts. They must also not be used in patients who are hypersensitive (allergic) to plants of the Asteraceae family.

Further information on the risks associated with these artichoke leaf 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.eu/Find medicine/Herbal medicines for human use.

How are artichoke leaf medicines approved in the EU?

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

Other information about artichoke leaf medicines

Further information on the HMPC assessment of artichoke leaf 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 artichoke leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.