



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2018
EMA/415131/2018
Committee on Herbal Medicinal Products (HMPC)

Milkthistle fruit

Silybum marianum (L.) Gaertn., fructus

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

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

What is milkthistle fruit?

Milkthistle fruit is the common name for the fruit of the plant *Silybum marianum* (L.) Gaertn.

The HMPC conclusions only cover milkthistle fruit preparations that are obtained by drying and comminuting (reducing into tiny pieces) or powdering the fruit or putting the plant material in a solvent (acetone, ethanol, ethyl acetate or methanol) to dissolve compounds and form a liquid extract. The solvent is then partially or completely evaporated to obtain soft or dry extracts.

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

Milkthistle fruit 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 milkthistle fruit preparations can be used for relief of symptoms of digestive disorders, sensation of fullness and indigestion and to support liver function, after serious conditions have been excluded by a medical doctor.

Milkthistle fruit medicines should only be used in adults and if symptoms last longer than 2 weeks or get worse while taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take milkthistle 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 milkthistle fruit medicines?

The HMPC conclusions on the use of these milkthistle fruit medicines for digestive disorders and to support liver function 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 several clinical studies with milkthistle fruit involving patients with liver disorders. Although the studies indicated that milkthistle fruit may have positive effects on liver function and improve symptoms, firm conclusions could not be drawn due to poor study design, small number of patients and differences in dose levels and duration of treatment. Therefore, the HMPC conclusions on the use of these milkthistle fruit 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 milkthistle fruit medicines?

Side effects have been reported with milkthistle fruit. These include mild gut symptoms such as dry mouth, nausea, upset stomach, stomach irritation and diarrhoea. Headache, allergic reactions (including skin inflammation, itching, skin or nettle rash, sudden severe allergic reaction and asthma) may also occur. The frequency is not known.

Milkthistle fruit medicines must not be used in patients who are hypersensitive (allergic) to milkthistle or plants of the Asteraceae family.

Further information on the risks associated with these milkthistle 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: ema.europa.eu/medicines/herbal/silybi-mariani-fructus.

How are milkthistle fruit medicines approved in the EU?

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

Other information about milkthistle fruit medicines

Further information on the HMPC assessment of milkthistle fruit medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/medicines/herbal/silybi-mariani-fructus. For more information about treatment with milkthistle fruit medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.