

16 January 2019 EMA/833739/2018

Wild strawberry leaf

Fragaria vesca L., Fragaria moschata Weston, Fragaria viridis Weston and Fragaria x ananassa (Weston) Duchesne ex Rozier, folium

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

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

What is wild strawberry leaf?

Wild strawberry leaf is the common name for the leaf of the plants *Fragaria vesca* L., *Fragaria moschata* Weston, *Fragaria viridis* Weston and *Fragaria x ananassa* (Weston) Duchesne ex Rozier.

The HMPC conclusions only cover wild strawberry leaf preparations that are obtained by comminuting the leaves (reducing them into tiny pieces).

Herbal medicines containing this wild strawberry leaf preparation are usually available as herbal tea to be drunk.

Wild strawberry 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 its long-standing use, this wild strawberry leaf preparation can be used to increase urine production in patients with minor problems affecting the urinary tract (structures that carry urine) and to relieve symptoms of mild diarrhoea.

Wild strawberry leaf medicines should only be used in adults and adolescents from 12 years of age. If symptoms last longer than 2 weeks while taking the medicine for minor urinary complaints or longer than 3 days for mild diarrhoea, a doctor or a qualified healthcare practitioner should be consulted.



Detailed instructions on how to take wild strawberry 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 wild strawberry leaf medicines?

The HMPC conclusions on the use of these wild strawberry leaf medicines for urinary complaints or diarrhoea 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 lack of studies with strawberry leaf in patients.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report under the section 'Documents' on the Agency's website: ema.eu/medicines/herbal/fragariae-folium.

What are the risks associated with wild strawberry leaf medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines.

Wild strawberry leaf medicines must not be used for urinary complaints in patients with conditions where a reduced fluid intake is recommended, such as severe heart or kidney disease.

Further information on the risks associated with these wild strawberry leaf medicines, including the appropriate precautions for their safe use, can be found in the monograph under the section 'Documents' on the Agency's website: ema.eu/medicines/herbal/fragariae-folium.

How are wild strawberry leaf medicines approved in the EU?

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

Other information about wild strawberry leaf medicines

Further information on the HMPC assessment of wild strawberry leaf medicines, including details of the Committee's conclusions, can be found under the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/fragariae-folium. For more information about treatment with wild strawberry leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.