



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Herbal medicine: summary for the public

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### Grapevine leaf

*Vitis vinifera* L., folium

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

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

#### **What is grapevine leaf?**

Grapevine leaf is the common name for the leaves of the plant *Vitis vinifera* L.

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

Herbal medicines containing these grapevine leaf preparations are usually available as herbal tea to be drunk, in solid forms to be taken by mouth and in semi-solid forms to be applied to the skin.

Grapevine 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 grapevine leaf preparations can be used for treatment of chronic (long-term) venous insufficiency, a condition associated with swollen legs, varicose veins and a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves.

The HMPC also concluded that, on the basis of its long-standing use, grapevine leaf preparations can be used for relief of discomfort and heaviness of legs related to minor problems with blood circulation in the veins, for relief of itching and burning associated with haemorrhoids (piles) after serious

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conditions have been excluded by a medical doctor, and for treatment of symptoms of skin capillary fragility.

Grapevine leaf medicines should only be used in adults. The recommended duration of treatment is 12 weeks for chronic venous insufficiency, although longer term use is possible after consulting a doctor. If symptoms last for more than 2 weeks when taking the medicine for minor blood circulation problems in the veins or for more than 1 week for haemorrhoids or skin capillary fragility, a doctor or healthcare practitioner should be consulted. Detailed instructions on how to take grapevine 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 grapevine leaf medicines?**

The HMPC conclusions on the use of grapevine leaf medicines for chronic venous insufficiency are based on their 'well-established use'. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered a number of clinical studies with grapevine leaf medicines for the treatment of chronic venous insufficiency. Some of the studies had positive results, showing improvements in symptoms, including reduction in leg swelling.

The HMPC conclusions on the use of these grapevine leaf preparations for minor blood circulation problems, haemorrhoids and skin capillary fragility 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.

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

### **What are the risks associated with grapevine leaf medicines?**

Side effects that have been reported with grapevine leaf medicines include hypersensitivity (allergic) skin reactions (including itching and reddening of the skin), nausea (feeling sick), stomach and gut complaints, and headache. Their frequency is unknown.

Further information on the risks associated with these grapevine 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.europa.eu/Find\\_medicine/Herbal\\_medicines\\_for\\_human\\_use](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use).

### **How are grapevine leaf medicines approved in the EU?**

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

### **Other information about grapevine leaf medicines**

Further information on the HMPC assessment of grapevine 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](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use). For more information about treatment

with grapevine leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.