



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Rupturewort

Herniaria glabra L., *H. hirsuta* L. and *H. incana* Lam., herba

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

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

What is rupturewort?

Rupturewort is the common name for the flowering above-ground parts of the plants *Herniaria glabra* L., *H. hirsuta* L. or *H. incana* Lam.

The HMPC conclusions only cover rupturewort preparations that are obtained by drying and comminuting (reducing into tiny pieces) the flowering parts of a single species or a mixture of them.

Herbal medicines containing rupturewort preparations are usually available as herbal tea to be drunk.

Rupturewort 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 rupturewort preparations can be used for minor problems affecting the urinary tract (structures that carry urine) to increase the production of urine and flush the urinary tract.

Rupturewort medicines should only be used in adults. If the symptoms persist longer than 2 weeks, a doctor or another qualified health care practitioner should be consulted. Detailed instructions on how to take rupturewort medicines and who can use them can be found in the package leaflet that comes with the medicine.

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What evidence supports the use of rupturewort medicines?

The HMPC conclusions on the use of these rupturewort preparation medicines for minor problems affecting the urinary tract are based on their 'traditional use' in this condition. 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 rupturewort medicines?

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

Rupturewort preparation medicines must not be used in conditions where a reduced fluid intake is recommended, such as severe heart or kidney disease.

Further information on the risks associated with these rupturewort medicines, including the appropriate precautions for their safe use, can be found in the monograph which is published on the Agency's website under the section 'Documents': ema.europa.eu/medicines/herbal/herniariae-herba.

How are rupturewort medicines approved in the EU?

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

Other information about rupturewort medicines

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