



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2018
EMA/181295/2018

Herbal medicine: summary for the public

Bearberry leaf

Arctostaphylos uva-ursi (L.) Spreng., folium

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

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

What is bearberry leaf?

Bearberry leaf is the common name for the leaves of the plant *Arctostaphylos uva-ursi* (L.) Spreng.

The HMPC conclusions only cover bearberry leaf preparations which are obtained by drying and comminuting (reducing into tiny pieces) or powdering the leaves, or by using a technique to extract compounds by putting the plant material in a solvent (such as ethanol or water) to dissolve compounds and form a liquid extract. For dry extracts, the solvent is then evaporated.

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

Bearberry 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, these bearberry leaf preparations can be used for relief of symptoms of mild, recurrent infections in the lower urinary tract (the structure that carries urine), such as a burning sensation when passing urine and/or frequently passing urine.

Bearberry leaf preparations should only be used after serious conditions have been excluded by a doctor. These medicines should only be used in adult women. They should not be taken for longer than one week and if symptoms last for more than four days or worsen during the use of the medicine a



doctor or a qualified healthcare professional should be consulted. Detailed instructions on how to take bearberry 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 bearberry leaf medicines?

The HMPC conclusions on the use of these bearberry leaf medicines for lower urinary tract infections 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 considered laboratory studies which showed bearberry leaf preparations to have antibacterial action. No clinical studies are available with preparations containing only bearberry leaf.

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

What are the risks associated with bearberry leaf medicines?

Women with kidney disorders must not take bearberry leaf medicines. Nausea, vomiting and stomach ache are side effects that have been reported with bearberry leaf medicines.

Further information on the risks associated with these bearberry 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.

How are bearberry leaf medicines approved in the EU?

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

Other information about bearberry leaf medicines

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