



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Herbal medicine: summary for the public

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### Dried bilberry fruit

*Vaccinium myrtillus* L., fructus siccus

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

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

#### **What is dried bilberry fruit?**

Dried bilberry fruit is the common name for the dried fruit of the plant *Vaccinium myrtillus* L.

Dried bilberry fruit preparations are obtained by comminuting (reducing into tiny pieces) the ripe, dry fruit.

Herbal medicines containing dried bilberry fruit are usually available as herbal tea to be drunk or used to rinse the mouth.

Dried bilberry fruit can 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, dried bilberry fruit can be used for the treatment of mild diarrhoea and minor inflammation of the lining of the mouth.

Dried bilberry fruit should only be used in adults and children over the age of 12 years. A doctor or a qualified healthcare practitioner should be consulted if symptoms persist for more than 3 days when treating mild diarrhoea or for more than 1 week for inflammation of the lining of the mouth. Detailed instructions on how to take dried bilberry 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 dried bilberry fruit medicines?**

The HMPC conclusions on the use of dried bilberry fruit medicines for treating mild diarrhoea and minor inflammation of the lining of the mouth 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 clinical studies with dried bilberry fruit for these uses. Results from laboratory studies, although limited, indicate that the tannins in dried bilberry fruit have antimicrobial and astringent properties which can explain the traditional use of the dried fruit for treating mild diarrhoea and minor inflammation of the lining of the mouth.

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

## **What are the risks associated with dried bilberry fruit medicines?**

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

Further information on the risks associated with dried bilberry 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/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

## **How are dried bilberry fruit medicines approved in the EU?**

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

## **Other information about dried bilberry fruit medicines**

Further information on the HMPC assessment of dried bilberry 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/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with dried bilberry fruit medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.