



16 January 2019  
EMA/836995/2018

## Gentian root

*Gentiana lutea* L., radix

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

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

### What is gentian root?

Gentian root is the common name for the root of the plant *Gentiana lutea* L.

The HMPC conclusions only cover gentian root preparations that are obtained by drying and comminuting (reducing into tiny pieces) the root or by putting the plant material in a solvent (ethanol) to dissolve compounds and form a liquid extract. The solvent may then be evaporated to obtain a dry extract.

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

Gentian root 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 gentian root preparations can be used for temporary loss of appetite and for mild stomach and gut complaints such as indigestion.

Gentian root medicines should only be used in adults. If symptoms last longer than 2 weeks or worsen while taking the medicine, a doctor or healthcare practitioner should be consulted. Detailed instructions on how to take gentian root medicines and who can use them can be found in the package leaflet that comes with the medicine.



## **What evidence supports the use of gentian root medicines?**

The HMPC conclusions on the use of these gentian root medicines for temporary loss of appetite and for mild stomach and gut complaints 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 also considered an observational study involving 205 patients with mild stomach and gut complaints treated with gentian root. Although results of the study suggested that gentian root improved symptoms, since it was not compared with another treatment it was not possible to draw firm conclusions. Therefore, the HMPC conclusions on the use of these gentian root medicines are based on their long-standing use.

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.europa.eu/medicines/herbal/gentianae-radix](http://ema.europa.eu/medicines/herbal/gentianae-radix).

## **What are the risks associated with gentian root medicines?**

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

Further information on the risks associated with these gentian root 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.europa.eu/medicines/herbal/gentianae-radix](http://ema.europa.eu/medicines/herbal/gentianae-radix).

## **How are gentian root medicines approved in the EU?**

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

## **Other information about gentian root medicines**

Further information on the HMPC assessment of gentian root 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/gentianae-radix](http://ema.europa.eu/medicines/herbal/gentianae-radix). For more information about treatment with gentian root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.