



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Herbal medicine: summary for the public

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### Comfrey root

*Symphytum officinale* L., radix

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

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

#### **What is comfrey root?**

Comfrey root is the common name for the root of the plant *Symphytum officinale* L.

This summary covers Comfrey root medicines containing a specific herbal preparation, which is obtained by ethanol extraction (a technique used to extract compounds from plant material by dissolving them in alcohol).

Herbal medicines containing this comfrey root preparation are available in semi-solid forms (such as creams or ointments) to be applied to the skin.

#### **What are the HMPC conclusions on its medicinal uses?**

The HMPC concluded that, on the basis of its long-standing use, these comfrey root medicines can be used for the relief of symptoms of minor sprains and bruises.

These medicines should only be used in adults and should not be taken for longer than 10 days. Detailed instructions on how to take comfrey root medicines and who can use them can be found in the package leaflet that comes with the medicine.

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<sup>1</sup> Minor correction in "What evidence supports the use of comfrey root medicines"



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

The HMPC conclusions on the use of comfrey root medicines for the relief of symptoms of minor sprains and bruises are based on their 'traditional use' in these conditions. 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 the well documented use of comfrey root for the relief of symptoms of minor sprains and bruises. The HMPC also noted 4 clinical studies carried out with a different comfrey preparation (not covered by this summary). These studies suggested a reduction in swelling and pain in patients using this herbal preparation for sprains and bruises. However, since the exact composition of the herbal preparation used in these studies is not known, these data were not taken into account and the HMPC conclusions on the use of comfrey root medicines are based on their long-standing use.

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

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

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

Comfrey root contains substances known as pyrrolizidine alkaloids, which have toxic effects on the liver when taken by mouth. No significant risk is expected when comfrey root medicines are used on the skin for short periods. However, the amount of pyrrolizidine alkaloids has to be specified in each comfrey root medicine and patients should not be exposed to more than 0.35 microgram of pyrrolizidine alkaloids per day.

Further information on the risks associated with comfrey root 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 comfrey root medicines approved in the EU?**

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

## **Other information about comfrey root medicines**

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