

20 September 2016
EMA/424238/2016

Herbal medicine: summary for the public

Primula root

Primula veris L. and/or *Primula elatior* (L.) Hill, radix

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

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

What is primula root?

Primula root is the common name for the underground parts of the plant *Primula veris* L. and/or *Primula elatior* (L.) Hill.

The HMPC conclusions only cover primula root preparations which are obtained by drying and comminuting (reducing into tiny pieces) the underground parts or using a technique to extract compounds by putting the plant material in a solvent (such as ethanol or methanol) to dissolve compounds and form a liquid extract. The solvent is then either fully or partially evaporated to obtain a dry or soft extract.

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

Primula 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 primula root preparations can be used as an expectorant (a medicine that helps bring up phlegm) for coughs associated with colds.

Most primula root preparations should only be used in adults and adolescents over the age of 12 years. Some specific preparations may be used in children between 4 and 12 years of age. If symptoms last

longer than one week or worsen during the use of the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take primula 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 primula root medicines?

The HMPC conclusions on the use of these primula root medicines for coughs 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 primula root increased production of airway secretions, making phlegm less thick and easier to expel. There are no clinical studies with preparations containing primula root only.

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

What are the risks associated with primula 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 primula 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.

How are primula root medicines approved in the EU?

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

Other information about primula root medicines

Further information on the HMPC assessment of primula 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. For more information about treatment with primula root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.