24 July 2018
EMA/421887/2018

Pale coneflower root

Echinacea pallida (Nutt.) Nutt., radix

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

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

What is pale coneflower root?

Pale coneflower root is the common name for the root of the plant *Echinacea pallida* (Nutt.) Nutt.

The HMPC conclusions only cover pale coneflower root preparations that are obtained 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 pale coneflower root preparations are usually available in solid and liquid forms to be taken by mouth or to be applied to the lining of the mouth.

Pale coneflower 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 their long-standing use, these pale coneflower root preparations can be used for relief of symptoms of the common cold.

Pale coneflower root medicines should only be used in adults and adolescents from the age of 12 years. Treatment should start at the first signs of a cold. If symptoms last longer than 10 days, or if they get worse or a high fever occurs while taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take pale coneflower root medicines and who can use them can be found in the package leaflet that comes with the medicine.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What evidence supports the use of pale coneflower root medicines?

The HMPC conclusions on the use of these pale coneflower root medicines for relief of symptoms of the common cold 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 a study involving 160 patients with flu-like infections where pale coneflower root was compared with placebo (a dummy treatment). Although a possible effect in reducing symptoms was observed, firm conclusions could not be drawn due to lack of data on the preparation and composition of the pale coneflower root extract used in the study and further shortcomings of the study. Therefore, the HMPC conclusions on the use of these pale coneflower 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 pale coneflower root medicines?

Hypersensitivity (allergic) reactions including skin reactions may occur with pale coneflower medicines. Their frequency is not known.

Patients who are hypersensitive to pale coneflower and to other plants of the Asteraceae (Compositae) family must not take pale coneflower root medicines.

Further information on the risks associated with these pale coneflower 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 pale coneflower root medicines approved in the EU?

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

Other information about pale coneflower root medicines

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