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Pelargonium root

Pelargonium sidoides DC and/or Pelargonium reniforme Curt., radix

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

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

What is pelargonium root?

Pelargonium root is the common name for the root of the plants *Pelargonium sidoides* DC and *Pelargonium reniforme* Curt.

The HMPC conclusions only cover pelargonium root preparations that are obtained by putting the plant material in a solvent (such as ethanol) to dissolve compounds and form a liquid extract. The solvent may then be evaporated to obtain a dry extract.

Herbal medicines containing these pelargonium root preparations are usually available in liquid or solid forms to be taken by mouth.

Pelargonium 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 pelargonium root preparations can be used to treat the symptoms of the common cold.

Pelargonium root medicines should only be used in patients from the age of 6 years. If symptoms last longer than 1 week or worsen while taking the medicine, a doctor or qualified healthcare practitioner should be consulted. Detailed instructions on how to take pelargonium root medicines and who can use them can be found in the package leaflet that comes with the medicine.

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What evidence supports the use of pelargonium root medicines?

The HMPC conclusions on the use of these pelargonium root medicines for treating common colds 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 3 studies involving patients with acute bronchitis (inflammation of the airways in the lungs), where pelargonium root was compared with placebo (a dummy treatment). Although a possible effect in improving symptoms of bronchitis such as cough was observed, firm conclusions could not be drawn as there were weaknesses in the design and outcome of the studies. Therefore, the HMPC conclusions on the use of these pelargonium 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 pelargonium root medicines?

Very rare side effects (seen in less than 1 patient in 10,000) have been reported with pelargonium root medicines. These include mild gut complaints such as diarrhoea, discomfort around the stomach area, nausea or vomiting, difficulty swallowing, mild nasal and gum bleeding and allergic reactions. Liver problems have also been reported but the frequency is not known.

Further information on the risks associated with these pelargonium 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: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>.

How are pelargonium root medicines approved in the EU?

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

Other information about pelargonium root medicines

Further information on the HMPC assessment of pelargonium root medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>. For more information about treatment with pelargonium root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.