



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Arctic root

Rhodiola rosea L., rhizoma et radix

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

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

What is arctic root?

Arctic root is the common name for the underground stem (or rhizome) and root of the plant *Rhodiola rosea* L. The plant is cultivated or gathered to obtain the underground organs (root and rhizome) for medicinal use.

Arctic root preparations are obtained from the dried extracts prepared by ethanol extraction (a technique used to extract compounds from plant material by dissolving them in ethanol).

Herbal medicines containing arctic root are usually available in solid forms to be taken by mouth.

Arctic root can 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, arctic root can be used for the temporary relief of symptoms of stress, such as fatigue and sensation of weakness.

Arctic root medicines should only be used in adults over the age of 18 years and should not be taken for longer than two weeks without seeking medical advice. Detailed instruction on how to take arctic 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 arctic root medicines?

The HMPC conclusions on the use of arctic root medicines 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 clinical studies of small size that have been carried out to investigate the effects of arctic root medicines in adults suffering from stress and fatigue as compared with placebo (a dummy treatment). Although a possible effect in the temporary relief of symptoms of stress was observed, several shortcomings have been identified in these studies. Therefore, the HMPC conclusions on the use of arctic 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 arctic root medicines?

Arctic root medicines are generally well tolerated. At the time of the HMPC assessment, no side effects had been reported with these medicines.

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

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

Other information about arctic root medicines

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