



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Restharrow root

Ononis spinosa L., radix

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

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

What is restharrow root?

Restharrow root is the common name for the root of the plant *Ononis spinosa* L.

The HMPC conclusions only cover restharrow root preparations which are obtained by drying and comminuting (reducing into tiny pieces) the root.

Herbal medicines containing this restharrow root preparation are usually available as herbal tea to be drunk.

Restharrow 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, this restharrow root preparation can be used for minor complaints affecting the urinary tract (structures that carry urine) to increase the production of urine to achieve flushing of the urinary tract.

Restharrow root medicines should only be used in adults and adolescents over the age 12 years. Restharrow root medicines should be taken with plenty of liquid. If symptoms last longer than 1 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 restharrow 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 restharrow root medicines?

The HMPC conclusions on the use of these restharrow root medicines for minor urinary complaints 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 showing restharrow root increases urine production. No studies in patients have been carried out with restharrow root.

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

What are the risks associated with restharrow root medicines?

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

Restharrow root medicines must not be taken by patients with conditions where reduced fluid intake is recommended (such as severe heart or kidney disease).

Further information on the risks associated with these restharrow 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: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000199.jsp&mid=WC0b01ac058001fa1d

How are restharrow root medicines approved in the EU?

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

Other information about restharrow root medicines

Further information on the HMPC assessment of restharrow root medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's

website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000199.jsp&mid=WC0b01ac058001fa1d. For more information about treatment with restharrow

root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.