

12 July 2013 EMA/HMPC/261736/2013 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Woody nightshade stem

Solanum dulcamara L., stipites

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

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

What is woody nightshade stem?

Woody nightshade stem is the common name for the stems of the plant *Solanum dulcamara* L. The plant is cultivated or gathered to obtain the stems for medicinal use.

Woody nightshade stem preparations are obtained by comminuting (reducing into tiny pieces) the stems of two- to three-year old plants, harvested in spring before the leaves develop, or in late autumn after the leaves have dropped.

Herbal medicines containing comminuted woody nightshade stem are usually available for soaking in water (infusion or decoction) to produce a liquid to be applied to the skin.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, woody nightshade stem can be used for the relief of the symptoms of repeated episodes of mild eczema (itchy, red rash).

Woody nightshade stem should only be used in adults and should not be used if symptoms last for longer than two weeks without seeking advice from a qualified healthcare practitioner. Woody nightshade may be harmful if taken by mouth, and such use is not covered by the Committee's conclusions. Detailed instruction on how to use woody nightshade stem 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 woody nightshade stem medicines?

The HMPC conclusions on the use of woody nightshade stem medicines for mild eczema are based on their 'traditional use' in this condition. 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.

The HMPC took into account the well documented use of woody nightshade stem for this indication. For detailed information on the data assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with woody nightshade stem medicines?

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

Further information on the risks associated with woody nightshade stem 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 woody nightshade stem medicines approved in the EU?

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

Other information about woody nightshade stem medicines

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