

13 August 2013 EMA/HMPC/446032/2013 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

White horehound

Marrubium vulgare L., herba

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

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

What is white horehound?

White horehound is the common name for the plant *Marrubium vulgare L*. The plant is cultivated or gathered to obtain the above-ground parts for medicinal use.

White horehound preparations are obtained by comminuting (reducing into tiny pieces) or powdering the above-ground parts of the plant, by making a liquid extract or pressing the juice from the plant.

Herbal medicines containing white horehound are usually available in a comminuted form for herbal tea, or in solid or liquid forms to be taken by mouth.

White horehound 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, white horehound can be used in the following ways:

- as an expectorant (a medicine to help bring up phlegm) in patients with cough associated with a cold;
- for treating mild dyspepsia symptoms, such as bloating and flatulence;



• in patients with a temporary loss of appetite.

White horehound should only be used in adults and adolescents aged over 12 years. If symptoms of cough persist for longer than one week, patients should consult a qualified healthcare practitioner. For dyspepsia and loss of appetite, patients are advised to consult healthcare practitioner if symptoms last longer than two weeks. Detailed instruction on how to take white horehound medicines and who can use them can be found in the package leaflet that comes with the medicine.

What evidence supports the use of white horehound medicines?

The HMPC conclusions on the use of white horehound medicines in patients with cough, dyspepsia symptoms and loss of appetite 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 the well documented and longstanding use of white horehound in the approved indications. The HMPC noted that the bitter substances and essential oils the medicine contains may stimulate appetite and secretions from the lining of the airways. In addition, there were published experimental studies suggesting a number of properties that could plausibly help in patients with mild dyspepsia. For detailed information on the data assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with white horehound medicines?

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

Further information on the risks associated with white horehound 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 white horehound medicines approved in the EU?

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

Other information about white horehound medicines

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