



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Boldo leaf

Peumus boldus Molina, folium

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

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

What is boldo leaf?

Boldo leaf is the common name for the leaf of the plant *Peumus boldus* Molina.

The HMPC conclusions only cover boldo leaf preparations which are obtained by drying and comminuting (reducing into tiny pieces) the leaves or by putting the plant material in a solvent (water) to dissolve compounds and form a liquid extract. The solvent is then evaporated to obtain a dry extract.

Herbal medicines containing these boldo leaf preparations are usually available as herbal tea to be drunk and in solid forms to be taken by mouth.

Boldo leaf 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, these boldo leaf preparations can be used for the relief of symptoms of dyspepsia (indigestion) and mild spasms of the gut.

Boldo leaf medicines should only be used in adults. If symptoms last longer than 2 weeks or worsen while taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take boldo leaf medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of boldo leaf medicines?

The HMPC conclusions on the use of these boldo leaf medicines for dyspepsia and mild spasms of the gut 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 laboratory studies which showed that boldine, which is found in boldo leaf, can increase bile production. No studies in patients have been carried out with boldo leaf.

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

What are the risks associated with boldo leaf medicines?

Hypersensitivity (allergic) reactions have reported with these medicines.

Boldo leaf medicines must not be taken by patients with obstruction of the bile duct, cholangitis (inflammation of the bile duct), liver disease, gallstones and any other disorders of the bile ducts that require medical supervision and advice.

Further information on the risks associated with these boldo leaf 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 boldo leaf medicines approved in the EU?

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

Other information about boldo leaf medicines

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