

31 May 2016 EMA/269745/2016

Herbal medicine: summary for the public

Sandy everlasting

Helichrysum arenarium (L.) Moench, flos

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

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

What is Sandy everlasting?

Sandy everlasting is the common name for the flowers of the plant *Helichrysum arenarium* (L.) Moench.

The HMPC conclusions only cover a sandy everlasting preparation, which is obtained by drying and comminuting (reducing into tiny pieces) the flowers.

Herbal medicines containing this sandy everlasting preparation is usually available as herbal teas to be drunk.

Sandy everlasting 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 sandy everlasting preparation can be used for digestive disorders with a feeling of fullness and bloating.

Sandy everlasting medicines should only be used in adults. If symptoms last longer than two weeks during the use of the medicine a doctor or qualified healthcare practitioner should be consulted. Detailed instructions on how to take sandy everlasting medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of Sandy everlasting medicines?

The HMPC conclusions on the use of this sandy everlasting medicine for digestive disorders with a feeling of fullness and bloating are based on its '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.

The HMPC noted a lack of clinical studies with sandy everlasting. In its assessment, the HMPC considered studies in laboratory tests which supported an effect in increasing the flow of bile (a fluid produced in the liver which helps to break down fats) and reducing muscle contractions of the gall bladder (a small organ where bile is stored).

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

What are the risks associated with Sandy everlasting medicines?

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

Further information on the risks associated with these sandy everlasting 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.eu/Find medicine/Herbal medicines for human use.

How are Sandy everlasting medicines approved in the EU?

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

Other information about Sandy everlasting medicines

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