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## Herbal medicine: summary for the public

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### Marshmallow root

*Althaea officinalis* L., radix

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

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

#### **What is marshmallow root?**

Marshmallow root is the common name for the dried root of the plant *Althaea officinalis* L.

The HMPC conclusions cover marshmallow root preparations obtained by comminuting (reducing into tiny pieces) the roots or by macerating them to prepare a syrup. They also cover dry and liquid extracts. Extracts are obtained by using a technique to extract compounds by putting the plant material in a solvent (such as water or the alcohol ethanol) to dissolve compounds and form a liquid extract. For dry extracts, the solvent is then evaporated.

Herbal medicines containing these marshmallow root preparations are usually available as herbal tea to be drunk or in solid or liquid forms to be taken by mouth or to be applied in the mouth.

Marshmallow 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, these marshmallow root preparations can be used to treat irritation of the mouth or throat and associated dry cough. They can also be used to relieve mild discomfort of the stomach and gut.

For mouth or throat irritation and associated dry cough, marshmallow root medicines can usually be used in adults, adolescents and children over the age of 3 years. For relief of mild stomach and gut



discomfort, marshmallow root medicines can usually be used in adults and adolescents over the age of 12 years. However, medicines containing ethanol extracts of marshmallow root can only be used in adults due to lack of adequate data.

If symptoms last longer than 1 week during use of the medicine for mouth or throat irritation and associated dry cough, or longer than 2 weeks during use of the medicine for mild stomach and gut discomfort, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take marshmallow 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 marshmallow root medicines?**

The HMPC conclusions on the use of these marshmallow root preparations for mouth or throat irritation and associated dry cough, and mild stomach and gut discomfort are based on their 'traditional use' in these conditions. 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 two clinical studies with marshmallow root syrup in around 900 children with mouth and throat irritation and associated dry cough. Although an effect in reducing coughing was observed, firm conclusions could not be drawn since marshmallow root syrup was not compared with any other treatment in these studies. A further study in 63 adults with dry cough also indicated that marshmallow root drops reduced cough whereas no changes were seen in patients taking placebo (a dummy treatment). However, the herbal preparation used in the study was not sufficiently described. Therefore, the HMPC conclusions on the use of these marshmallow root medicines are based on their long-standing use.

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

### **What are the risks associated with marshmallow root 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 marshmallow 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: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

### **How are marshmallow root medicines approved in the EU?**

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

### **Other information about marshmallow root medicines**

Further information on the HMPC assessment of marshmallow root 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](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about

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