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## Herbal medicine: summary for the public

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### Thyme and primula root

*Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix

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

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

#### What are thyme and primula root?

Thyme is the common name for the aerial parts of the plants *Thymus vulgaris* L. or *Thymus zygis* L., and primula root is the common name for the underground parts of *Primula veris* L. or *Primula elatior* (L.) Hill.

The HMPC conclusions only cover combinations of certain thyme and primula root preparations which are obtained using a technique to extract compounds by putting the plant material in a solvent (such as ethanol or glycerol) to dissolve compounds and form a liquid extract. In some cases the solvent is then either partially or fully evaporated to obtain a soft or dry extract.

Herbal medicines containing combinations of these thyme and primula root preparations are usually available in liquid or solid forms to be taken by mouth.

Thyme and primula root preparations may also be found in additional combinations with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

#### What are the HMPC conclusions on their medicinal uses?

The HMPC concluded that certain thyme and primula root preparations can be used as an expectorant (a medicine that helps bring up phlegm) for productive (chesty) coughs in adults.



The HMPC also concluded that other thyme and primula root preparations can be used for coughs associated with colds based on long-standing use of these medicines. Some of these combinations may be used in adults and adolescents over 12 years of age, some others may be used also in children over 4 years of age.

If symptoms last longer than one week during the use of the medicine for chesty coughs a doctor or pharmacist should be consulted. If symptoms last longer than one week during the use of the medicine for coughs associated with colds a doctor or a qualified health care practitioner should be consulted. Detailed instructions on how to take thyme and primula root medicines and who can use them can be found in the package leaflet that comes with the medicine.

## **How do thyme and primula root work as a medicine?**

The way thyme and primula root work is not fully known, but laboratory studies indicate that thyme may have an action against microbes and a muscle relaxant effect while primula root may increase production of sputum in the airways, thereby diluting phlegm and helping to bring it up.

## **What evidence supports the use of thyme and primula root medicines?**

The HMPC conclusions on the use of certain thyme and primula root preparations for productive coughs are based on their 'well-established use'. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered a number of clinical studies with thyme and primula root showing that these medicines help reduce coughs in adults.

The HMPC conclusions on the use of certain other thyme and primula root preparations for coughs associated with colds 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 clinical studies with thyme and primula root medicines in children. However, firm conclusions could not be drawn as these studies did not use a control group. Therefore, the HMPC conclusions on the use of these thyme and primula root medicines for coughs associated with colds 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 thyme and primula root medicines?**

Stomach complaints and nausea may occur. The frequency is not known.

Further information on the risks associated with these thyme and primula 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_medicine/Herbal_medicines_for_human_use).

## **How are thyme and primula root medicines approved in the EU?**

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

### **Other information about thyme and primula root medicines**

Further information on the HMPC assessment of thyme and primula 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 thyme and primula root medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.