

12 July 2013 EMA/HMPC/296580/2012 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Ginger Zingiber officinale Roscoe, rhizoma

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

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

What is ginger?

Ginger is the common name for the whole or cut rhizome (underground stems) of the plant *Zingiber officinale*. The plant is cultivated or gathered to obtain the rhizome for medicinal use.

The herbal preparation is obtained by drying and powdering the rhizome. Herbal medicines containing ginger are usually available in solid forms and are taken by mouth.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that ginger can be used in adults to prevent nausea and vomiting in motion sickness.

It also concluded that, on the basis of its long-standing use, ginger can be used in adults to treat the symptoms of mild complaints affecting the stomach or gut (including bloating and flatulence), and in adults and children aged six and above to treat the symptoms of motion sickness.

Detailed instructions on how to take ginger-containing medicines and who can use them can be found in the package leaflet that comes with the medicine.

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How does ginger work as a medicine?

The exact way ginger acts on the stomach and gut is not fully known, but it is thought to work by blocking certain receptors for the hormone 5HT3, known as serotonin, which are involved in the contraction of the smooth muscles inside the stomach and gut. When serotonin attaches to these receptors it causes nausea and vomiting.

What evidence supports the use of ginger medicines?

The HMPC conclusions on the use of ginger medicines for the prevention of nausea and vomiting in motion sickness are based on their 'well-established use' in this indication. 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 ginger, looking at its effectiveness in treating different conditions. In particular, ginger has been compared with placebo (a dummy treatment) or other treatments in the prevention of nausea and vomiting in motion sickness. The results showed that ginger was more effective than placebo and as effective as other medicines in preventing motion sickness.

The HMPC conclusions on the use of ginger medicines for the treatment of symptoms of motion sickness and of mild complaints affecting the stomach or gut are based on their 'traditional use' in these indications. 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, these intended uses do not require medical supervision.

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

What are the risks associated with ginger medicines?

Common side effects (seen between 1 and 10 patients in 100) have been reported with ginger, mostly affecting the stomach and gut: stomach upset, eructation (belching), dyspepsia (heartburn) and nausea (feeling sick).

Further information on the risks associated with ginger 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: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>.

How are ginger medicines approved in the EU?

Any applications for the licensing of medicines containing ginger have to be submitted to the national authorities responsible for medicinal products, which will assess the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of ginger medicines in EU Member States should be obtained from the relevant national authorities.

Other information about ginger medicines

Further information on the HMPC assessment of ginger, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find</u>

medicine/Herbal medicines for human use. For more information about treatment with ginger, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.