

12 July 2013 EMA/HMPC/284498/2013 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Guarana seed

Paulinia cupana Kunth ex H.B.K. var. sorbilis (Mart.) Ducke, semen

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

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

What is guarana seed?

Guarana seed is the common name for the seed of the plant *Paulinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke. The plant is cultivated or gathered to obtain the seeds for medicinal use.

Guarana seed preparations are obtained by drying and powdering the seeds.

Herbal medicines containing guarana seed are usually available in solid forms to be taken by mouth.

Guarana seed can 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, guarana seed can be used for the relief of symptoms of fatigue (tiredness) and weakness.

Guarana seed should only be used in adults. If symptoms persist for longer than one week during the use of Guarana seed, a qualified healthcare practitioner should be consulted. Detailed instructions on how to take guarana seed medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of guarana seed medicines?

The HMPC conclusions on the use of guarana seed medicines for fatigue and weakness 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 considered studies on the effects of guarana seed on behaviour, which showed that it had a stimulant effect and led to improvements in symptoms of fatigue. For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with guarana seed medicines?

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

The HMPC recommended that these medicines should not be used in patients with stomach and gut ulcers, hyperthyroidism (overactive thyroid gland) or cardiovascular problems, such as hypertension (high blood pressure) and arrhythmias (heart rhythm problems).

Further information on the risks associated with guarana seed 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 guarana seed medicines approved in the EU?

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

Other information about guarana seed medicines

Further information on the HMPC assessment of guarana seed medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.eu/Find medicine/Herbal medicines for human use. For more information about treatment with guarana seed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.