

19 November 2015 EMA/324406/2015 *Corr.* ¹ Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Ginkgo leaf

Ginkgo biloba L., folium

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

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

What is ginkgo leaf?

Ginkgo leaf is the common name for the leaf of the plant Ginkgo biloba L.

This summary covers ginkgo leaf medicines containing a specific herbal preparation made by powdering the dried leaf or as dry extract. The dry extract is prepared using a technique to extract compounds from plant material by dissolving them in acetone which is then evaporated to obtain the dry extract.

Ginkgo leaf medicines containing these preparations are usually available in liquid and solid forms to be taken by mouth.

These ginkgo leaf preparations 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 ginkgo leaf medicines containing the dry extract can be used to improve the age-related cognitive impairment (worsening of mental abilities) and quality of life of adults with mild dementia.



¹ Corrected information in "What is ginkgo leaf" and "How does ginkgo leaf work"

The HMPC also concluded that, on the basis of their long-standing use, ginkgo leaf medicines containing the powdered leaf can be used for the relief of heaviness in the legs and the sensation of cold hands and feet that may occur with minor circulation problems. Medicines containing the powdered leaf should only be used after serious conditions have been excluded by a doctor.

Ginkgo leaf medicines should only be used in adults. If symptoms of dementia do not improve after 3 months or if symptoms worsen during the treatment, a doctor should be consulted. For the treatment of minor circulation problems, a doctor or a qualified healthcare practitioner should be consulted if symptoms persist for longer than 2 weeks. Detailed instructions on how to take ginkgo leaf medicines and who can use them can be found in the package leaflets that come with the medicines.

How does ginkgo leaf work as a medicine?

The exact way ginkgo leaf works in dementia is not fully understood but it is thought to protect brain cells from damage either directly or indirectly by regulating blood flow or by neutralising toxic forms of oxygen molecules (called oxygen free radicals).

What evidence supports the use of ginkgo leaf medicines?

The HMPC conclusions on the use of ginkgo leaf medicines to improve the age-related cognitive impairment and quality of life of adults with mild dementia 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 ginkgo leaf looking at its effectiveness in improving memory. The most relevant clinical trials performed in adults aged 50 years and above indicated that ginkgo leaf medicines containing the dry extract could have beneficial effects on cognitive function in mild dementia.

The HMPC conclusions on the use of ginkgo leaf medicines for minor circulation problems 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.

Although clinical studies with ginkgo leaf medicines for minor circulation problems are available, they were too limited to be used as evidence and the HMPC conclusions for this indication are based on the medicines' long-standing use. For further information, see the HMPC assessment report.

What are the risks associated with ginkgo leaf medicines?

At the time of the HMPC assessment, the most common side effect with ginkgo leaf medicines used for the treatment of mild dementia was headache (seen in more than 1 patient in 10). Bleeding such as bleeding in the eye, nose, brain or gut has also been reported. In patients who have a tendency to bleed or who use blood thinning medicines, ginkgo leaf medicines containing the dry extract should only be used after consulting a doctor. When used for minor circulation problems, gastrointestinal disorders (side effects affecting the gut), headaches and allergic reactions have been reported.

Further information on the risks associated with ginkgo leaf 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 ginkgo leaf medicines approved in the EU?

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

Other information about ginkgo leaf medicines

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