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Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Birch leaf

Betula pendula Roth and/or *Betula pubescens* Ehrh., folium

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

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

What is birch leaf?

Birch leaf is the common name for the leaves of the tree *Betula pendula* Roth and/or *Betula pubescens* Ehrh. or hybrids of both species. The leaves for medicinal use are obtained either from trees that have been cultivated or found in the wild.

Birch leaf preparations are obtained by powdering or comminuting (reducing into tiny pieces) the dried leaf, or as dry or liquid extracts. Extracts are prepared using a technique to extract compounds from plant material by dissolving them in a solvent (such as water or alcohol). For dry extracts the solvent is then evaporated to obtain the extract.

Herbal medicines containing birch leaf preparations are usually available as herbal tea or in solid and liquid forms to be taken by mouth.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, birch leaf medicines can be used in minor problems affecting the urinary tract (structures that carry urine) to increase the production of urine, in order to achieve flushing of the urinary tract.

Birch leaf medicines should only be used in adults and adolescents above 12 years of age. They are used over a period of 2 to 4 weeks. If symptoms persist during treatment, a doctor or a qualified

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healthcare practitioner should be consulted. Detailed instruction on how to take birch leaf medicines and who can use them can be found in the package leaflet that comes with the medicine.

What evidence supports the use of birch leaf medicines?

The HMPC conclusions on the use of birch leaf medicines to increase the production of urine are based on their 'traditional use' in minor urinary tract problems. 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 there are few clinical studies, including a study in 15 patients with urinary tract infections which suggested a positive effect on the urinary infection, data are too limited to be used as evidence. Hence, the HMPC conclusions on the use of birch leaf 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 birch leaf medicines?

Side effects that have been reported with birch leaf medicines include diarrhoea, feeling or being sick, and allergic reactions such as itching, rash and stuffy and runny nose. Their frequency is unknown.

Birch leaf medicines must not be used in patients who are hypersensitive (allergic) to birch leaf or birch pollen. They must also not be used in patient with conditions where a reduced fluid intake is recommended (such as severe heart or kidney disease).

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

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

Other information about birch leaf medicines

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