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Frangula bark

Rhamnus frangula L., cortex

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

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

What is frangula bark?

Frangula bark is the common name for the bark of the plant *Rhamnus frangula* L. (*Frangula alnus* Miller).

The HMPC conclusions only cover frangula bark preparations that are obtained by drying and comminuting (reducing into tiny pieces) the bark. The dried comminuted bark may also be put in a solvent (such as ethanol) to dissolve compounds and form an extract.

Herbal medicines containing these frangula bark preparations are standardised based on a group of compounds called hydroxyanthracene derivatives and usually available as herbal tea to be drunk and in solid and liquid forms to be taken by mouth.

Frangula bark preparations may 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 these frangula bark preparations can be used short term for occasional constipation.

Frangula bark medicines should only be used in adults and adolescents over the age of 12 years and should not be taken for longer than one week. If symptoms last or worsen while taking the medicine, a doctor or a pharmacist should be consulted. Detailed instructions on how to take Frangula bark medicines and who can use them can be found in the package leaflet that comes with the medicine.

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How does frangula bark work as a medicine?

The way frangula bark works is not fully known, but it is thought that due to its content of hydroxyanthracene derivatives it may stimulate movement of the large intestine resulting in faster transit. It may also prevent both water and salt absorption into the cells lining the colon (lower part of the gut) and also stimulate their secretion resulting in increased concentrations of fluid and salt in that part of the gut.

What evidence supports the use of frangula bark medicines?

The HMPC conclusions on the use of these frangula bark medicines for occasional constipation 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 frangula bark in combination with other laxatives looking at its effectiveness in treating constipation. There are no recent studies evaluating frangula bark alone; therefore the HMPC's conclusions on the effects of frangula bark to treat constipation are also based on experts' opinions, clinical experience as well as clinical and laboratory studies obtained with other anthranoid-containing laxatives such as senna leaf preparations showing a positive effect on constipation.

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

What are the risks associated with frangula bark medicines?

Frangula bark may produce tummy pain, spasm and liquid stools, especially in patients with irritable colon. These side effects may occur due to over-dosage.

Long term use may cause colouration of the gut lining (pseudomelanosis coli) which usually resolves when the patient stops taking the preparation.

Long term use may lead to water and salt imbalance and may result in albuminuria (protein in the urine) and haematuria (blood in the urine).

Yellow or red-brown (pH dependent) discolouration of urine may occur during treatment. It results from breakdown products and is not harmful.

The frequencies of these side effects are not known.

Frangula bark medicines must not be taken by patients with blockages and narrowing of the intestines, atony (loss of muscle strength), inflammation of the appendix, inflammatory bowel diseases (e.g. Crohn's disease, ulcerative colitis), belly pain of unknown origin, severe dehydration with water and salt loss. They must not be taken by children aged under 12 years and pregnant or breast-feeding women.

Further information on the risks associated with these frangula bark medicines, including the appropriate precautions for their safe use, can be found in the monograph which is published on the Agency's website under the section 'Documents': ema.europa.eu/medicines/herbal/frangula-bark.

How are frangula bark medicines approved in the EU?

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

Other information about frangula bark medicines

Further information on the HMPC assessment of frangula bark medicines, including details of the Committee's conclusions, can be found in the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/frangula-bark. For more information about treatment with frangula bark medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.