



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Linseed

Linum usitatissimum L., semen

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

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

What is linseed?

Linseed is the common name for the seeds of the plant *Linum usitatissimum* L. The dried, ripe seeds for medicinal use are obtained from plants that have been cultivated.

Herbal medicines containing linseed, also known as Lini semen, are to be taken by mouth.

Linseed 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 linseed can be used to treat habitual constipation or in conditions requiring the stool to be softer so it can pass more easily.

The HMPC also concluded that, on the basis of its long-standing use, linseed can be used to relieve mild gastrointestinal (stomach and gut) discomfort.

Linseed should only be used in adults and adolescent aged over 12 years. Advice should be taken from a doctor or a qualified healthcare professional if constipation persists after 3 days of using linseed or if mild gastrointestinal discomfort persists after 7 days of using linseed. Detailed instructions on how to take linseed medicines and who can use them can be found in the package leaflet that comes with the medicine.

¹ Corrected information in "What is linseed"



How does linseed work as a medicine?

Linseed swells with water in the gut to form a thick jelly-like substance (mucilage). This helps to make the stool softer and pass through the gut more easily. Also, the swelling effect of linseed widens the gut and this stretching effect speeds up passage of the stool through the gut.

It is likely that linseed mucilage coats the lining of the digestive tract and thus protects it from irritation. This effect may reduce gastrointestinal discomfort.

What evidence supports the use of linseed medicines?

The HMPC conclusions on the use of linseed for treating constipation are based on 'well-established use'. This means that there are bibliographic data providing scientific evidence of linseed's 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 showing linseed's effect on constipation and hard stool. The studies demonstrated that linseed reduced habitual constipation.

The HMPC conclusions on the use of linseed medicines for the relief of mild gastrointestinal discomfort are based on their 'traditional use' in this condition. 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 an early clinical study on linseed for the treatment of gastrointestinal discomfort is available, it was too limited to be used as evidence and the HMPC's conclusions for this indication are based on the medicines' long-standing use.

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

What are the risks associated with linseed medicines?

Common side effects (seen between 1 and 10 patients in 100) have been reported with linseed. These include bulging of the belly. Very rarely, allergic reactions, sometimes severe, have been reported.

Linseed must not be used in patients who have difficulty swallowing or have any throat problems.

For treating constipation, linseed must not be used in patients with a sudden change in bowel habit that persists for more than 2 weeks, or undiagnosed bleeding from the anus, or if constipation is not relieved despite the use of a laxative. It should also not be used in patients with abnormal constriction or blockage of the digestive tract, paralysis in the gut, or abnormal widening of the large intestine, or with diseases of the oesophagus (the tube between mouth and stomach).

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

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

Other information about linseed medicines

Further information on the HMPC assessment of linseed 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](http://ema.europa.eu/Find/medicine/Herbal_medicines_for_human_use). For more information about treatment with linseed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.