



The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL PROPOSAL FOR A CORE DATA FOR LINSEED

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Final Proposal for a core-data for Linseed (*Linum usitatissimum* L.)

The Working Party on Herbal Medicinal Products proposes the following core-data for Linseed (November 2003).

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Dried ripe seeds¹ of *Linum usitatissimum* L. for oral administration

3. PHARMACEUTICAL FORM

Herbal drug for oral preparation.

The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oral administration:

Herbal medicinal product

- a) for the treatment of habitual constipation²
- b) in conditions in which easy defecation with soft stool is desirable, e.g. in cases of painful defecation after rectal or anal surgery, anal fissures and haemorrhoids²
- c) as a demulcent preparation for the symptomatic treatment of gastrointestinal discomfort²

4.2 Posology and method of administration

Indications a and b):

Daily dose:

Elderly, adults, adolescents over 12 years of age: 10 – 15 g in 2 – 3 doses

Children from 6 to 12 years of age: Half the adult dose

Route of administration:

Take 10 – 15 g seeds with 150 ml liquids 2 – 3 times daily (29, 38, 42). Maintain adequate fluid intake at least 1,5 – 2 l per day. The product should be taken at least ½ to 1 hour before or after intake of other medicines. It should not be taken just before bedtime. The effect starts 12 – 24 hours later.

Duration of use:

¹ The material complies with the the European Pharmacopoeia

² Decision by majority

Because of the gradual mode of action of bulk forming laxatives, treatment should be continued for a minimum of 2 –3 days to ensure optimum benefit.

Indication c):

Single dose for adults, elderly and adolescents over 12 years of age:

For a mucilaginous preparation, soak 5 – 10 g whole or crushed seeds in 250 ml water and take this half an hour before eating during the day. If possible soak the seeds the evening before. The mucilaginous preparations may be consumed with or without the seeds.

4.3 Contraindications

Linseed is not to be used by patients with potential or existing intestinal blockage (ileus), by patients with faecal impaction and undiagnosed abdominal symptoms, abdominal pain, nausea and vomiting unless advised by a doctor, and by patients with a sudden change in bowel habit that persists for more than 2 weeks, rectal bleeding and failure to defecate following the use of a laxative.

Linseed is also not to be used by patients, who have difficulty in swallowing and by patients with known hypersensitivity to linseed.

4.4 Special warning and precautions for use

If the constipation does not resolve within 48 hours or if abdominal pain occurs or in case of any irregularity of faeces, the use of linseed should be discontinued and medical advice must be sought.

If there are any unclear or new gastrointestinal complaints a physician should also be consulted.

Warnings:

Take this product (child or adult dose) with at least 150 ml of water or other fluid. If this product is taken without adequate fluid, it may already swell in the mouth or in the oesophagus. This bulk may block the throat or oesophagus and may cause choking. Bezoar formation and intestinal obstruction may occur in case adequate fluid intake is not maintained. This product should not be taken with difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek medical attention immediately. Treatment of debilitated patients, elderly and children requires supervision.

As there is no sufficient experience available,

- use is not recommended in children below the age of 6 years for indications a and b);
- use is not recommended in children below the age of 12 years for indication c).

4.5 Interaction with other medicinal products and other forms of interaction

Enteral absorption of concomitantly administered medicines may be delayed by bulk forming laxatives such as linseeds.

For this reason the product should not be taken ½ to 1 hour before or after intake of other drugs.

Bulk producers and medicinal products against diarrhoea, which inhibit the peristaltic movement, may not be used at the same time because this can cause an ileus.

4.6 Pregnancy and lactation

As data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution.

There are no reports of any harmful or deleterious effects during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Meteorism, occurring with the use of the product, is common.

Reactions of hypersensitivity including anaphylaxis-like reactions may occur very rarely.

4.9 Overdose

Overdose with linseed may cause intestinal obstruction.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Laxatives Bulk Producers

ATC-Code: A 06 AC

The active ingredient linseed consists of the dried, ripe seeds of *Linum usitatissimum* L.

The seeds contain nearly 25 % of bulk materials (3 – 6 % of mucilage, 4 – 7 % of alimentary fibres).

The laxative effects of linseed have long been recognized empirically and shown in animal and clinical investigations. These effects are attributed to the bulk materials and in particular to the mucilage that binds with water and swells to form a demulcent gel in the intestine. Water is held back in the intestine due to the swelling of the mucilage. Faeces become softer. The volume of the intestinal content increases and causes a stretch stimulus, which effects a decrease in transit time. The swollen mass of mucilage forms a lubrication layer facilitating the transit of intestinal content.

Crushed seeds do not always cause a stretch stimulus because the increase of the volume may already start in the stomach. Whole or „bruised seeds“ have a retarded increase of the volume.

Level of evidence:

Indications a) and b) : the use as a laxative is made plausible by information from clinical studies and pharmacological data (level III).

Indication c) : the effect as a demulcent preparation is attributed to the protective effect on the mucosa by the coating action of the mucilage (level IV).

5.2 Pharmacokinetic properties

One part of the bulk materials in linseed is defaecated, the other part is fermentated in the colon by bacteria. This process of fermentation can produce gas and flatulence. The predominant products of fermentation are short chain fatty acids (SCFA), which are mainly resorbed. A key marker of fermentation is an increase in the concentration of short-chain fatty acids. These acids can serve as nutrients for those cells forming the colonic mucosa.

Progress of action: linseed usually acts within 12 to 24 hours. Sometimes the maximum effect is not reached before 2 or 3 days.

5.3 Preclinical safety data

Linseed contains 20 – 50 mg cyanide/100 g in form of the cyanogenic diglycosides linustatin and neolinustatin. Intoxication signs in human are caused neither by a unique dosage of 100 g linseed nor by a chronic dose of 45 – 50 g daily for 4 – 6 weeks.

The enzyme thiosulfate sulfur transferase (rhodanase) catalyzes the change of cyanide into thiocyanate (rhodanide), which is 200 times less toxic as cyanide. The chronic taking of linseed causes a cumulation of thiocyanate, which can be compared with the blood level of thiocyanate in heavy smokers.

6 Date of compilation

4 November 2003