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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:
LINSEED (LINUM, SEMEN)**

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**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:
LINSEED (LINUM, SEMEN)**

Scientific name of the plant	
<i>Linum usitatissimum</i> L.	
Botanical family	
Linaceae	
Common name in all EU official languages	
ES (español): Semilla de Lino; Linaza	MT (Malti): Żerriegħa tal-Kittien
CS (ceština): lněné semeno	NL (Nederlands): lijnzaad
DA (dansk): Hørfrø	PL (polski): nasienie lnu
DE (Deutsch): Leinsamen	PT (português): Sementes de Linho
ET (eesti keel): Lina seeme	SK (slovenčina):
EL (elliniká):	SL (slovenscina): navadni lan
EN (English): Linseed	FI (suomi): pellavansiemen
FR (français): graine de Lin	SV (svenska): linfrö
IT (italiano):	IS (islenska):
LV (latviešu valoda): Linu sēklas	NO (norsk): linfrø
LT (lietuviu kalba):	BG (bulgarski):
HU (magyar): lenmag	RO (romana): samanta de in
Herbal preparation(s)	
Dried ripe seeds of <i>Linum usitatissimum</i> L.	
European Pharmacopoeia monograph reference	
Lini semen (04/2005:0095)	
Traditional use	
Traditional herbal medicinal product for use as a demulcent preparation for the symptomatic treatment of gastrointestinal discomfort exclusively based on long-standing use.	
Specified strength	
Please see 'Specified posology'	
Specified posology	
Adolescents over 12 years of age, adults, elderly	
Single dose: 5 – 10 g whole or broken seeds in 250 ml water.	
Route of administration	
Oral use	

For a mucilaginous preparation, soak 5 – 10 g whole or broken 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.

A minimal definite period can be given in which the seeds have to be soaked. If it is proved for the specific preparation that the seeds do not swell more, the wordings in the underlying sections concerning bulk formers (i.e. contraindications, special warnings, interactions, undesirable effects) can be omitted.

Duration of use or any restrictions on the duration of use

No specific data

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

The use as a demulcent preparation for the symptomatic treatment of gastrointestinal discomfort is attributed to the protective effect on the mucosa by the coating action of the mucilage.

Any other information necessary for the safe use

Contraindications

Patients with known hypersensitivity to Linseed should not use Linseed preparations.

Linseed is not to be used by patients with potential or existing intestinal blockage (ileus), paralysis of the intestine or megacolon and by patients with a sudden change in bowel habit that persists for more than 2 weeks.

Linseed is not to be used by patients with abnormal constrictions on the oesophagus, cardia or gastrointestinal tract.

Linseed is also not to be used by patients, who have difficulty in swallowing.

Special warnings and precautions for use

Because there is no sufficient experience available, use is not recommended in children below the age of 12 years.

If the symptoms persist for more than 1 week or worsen during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur, a doctor or a qualified health care practitioner should be consulted.

Linseed is not to be used by patients with faecal impaction and undiagnosed abdominal symptoms, abdominal pain, nausea and vomiting unless advised by a doctor because these symptoms can be signs of a potential or existing intestinal blockage.

Warnings:

The patient should take this product with at least 150 ml of water or other fluid. If this product is taken without adequate fluid, 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 by patients with difficulties in swallowing. If the patient experience chest pain, vomiting, or difficulties in swallowing or breathing after taking this product, medical attention should be sought immediately. Treatment of debilitated patients and elderly requires supervision.

Investigations in healthy women suggest that there might be an oestrogenic effect of Linseed. As there are no sufficient data available of the oestrogenic effect, use is not recommended in women suffering from hormonally dependent tumours.

Interactions with other medicinal products and other forms of interaction

Enteral absorption of concomitantly administered medicines may be delayed by a demulcent preparation of Linseed.

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

In order to decrease the risk of gastrointestinal obstruction (ileus) Linseed should be used with caution

with medicinal products known to inhibit the peristaltic movement (e.g. morphinomimetics, loperamide) and only under medical supervision.

Pregnancy and lactation

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

Investigations in healthy women suggest that there might be an oestrogenic effect of Linseed.

As there are no sufficient data available, use is not recommended during pregnancy and lactation and in women of child-bearing potency.

Effects on ability to drive and use machines

None known.

Undesirable effects

Meteorism, occurring with the use of the product, is common. Reactions of hypersensitivity including anaphylaxis-like reactions may occur very rarely.

Overdose

Overdose with Linseed may cause intestinal obstruction.