



10 March 2015
EMA/HMPC/377675/2014
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Linum usitatissimum* L., semen

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2005 June 2005 September 2005
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	20 September 2005
End of consultation (deadline for comments).	31 January 2006
Rediscussion in MLWP	May 2006 July 2006
Adoption by HMPC Monograph (EMA/HMPC/340849/2005) AR (EMA/HMPC/167395/2006) List of references (EMA/HMPC/167397/2006) Overview of comments received during the public consultation (EMA/HMPC/66042/2006) HMPC Opinion (EMA/HMPC/353205/2006)	13 July 2006
First systematic review	
Discussion in MLWP	July 2014 September 2014
Adoption by HMPC	10 March 2015
Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; well-established medicinal use; traditional use; <i>Linum usitatissimum</i> L., semen; Lini semen; linseed



BG (bulgarski): Ленено семе	LT (lietuvių kalba): Linų sėmenys
CS (čeština): Lněné semeno	LV (latviešu valoda): Linu sēklas
DA (dansk): Hørfrø	MT (Malti): Żerriegħa tal-Kittien
DE (Deutsch): Leinsamen	NL (Nederlands): Lijnzaad
EL (elliniká): Σπέρματα λιναριού- λίνου σπέρμα	PL (polski): Nasienie lnu
EN (English): Linseed	PT (português): Linho, semente
ES (español): Lino, semilla de	RO (română): sămânță de in
ET (eesti keel): linaseeme	SK (slovenčina): Semeno ľanu
FI (suomi): pellava, siemen	SL (slovenščina): seme navadnega lana
FR (français): Lin (graine de)	SV (svenska): Linfrö
HU (magyar): Lenmag	<i>IS (íslenska):</i>
HR (hrvatski): laneno sjeme	<i>NO (norsk): Linfrø</i>
IT (italiano): Lino seme	

European Union herbal monograph on *Linum usitatissimum* L., semen

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2}

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended <i>Linum usitatissimum</i> L., semen (linseed) i) Herbal substance As defined in the Ph. Eur. monograph ii) Herbal preparations not applicable	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Linum usitatissimum</i> L., semen (linseed) i) Herbal substance As defined in the Ph. Eur. monograph ii) Herbal preparations not applicable

3. Pharmaceutical form

Well-established use	Traditional use
Herbal substance for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	Herbal substance for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product for the treatment of habitual constipation or in conditions in which easy defaecation with soft stool is desirable.	Traditional herbal medicinal product used as a demulcent preparation for the symptomatic relief of mild gastrointestinal discomfort. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref.: 0095).

4.2. Posology and method of administration

Well-established use	Traditional use
<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>10 - 15 g,</p> <p>Daily dose: 2 - 3 times daily</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the constipation does not resolve within 3 days, a doctor or a pharmacist should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p> <p>Take 10 - 15 g seeds with 150 ml water, milk, fruit juice or similar aqueous liquid 2 - 3 times daily; then maintain adequate fluid intake. The product should be taken during the day at least ½ to 1 hour before or after intake of other medicines. The effect starts 12 - 24 hours later.</p> <p>Warning: not to be taken immediately prior to bedtime.</p>	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>5 – 10 g in 250 ml water</p> <p>Daily dose: up to three times during the day</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist for longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p> <p>For a mucilaginous preparation, soak 5 - 10 g whole or broken seeds in 250 ml water for at least <x min> and take this half an hour before eating. At the time of consumption the process of swelling has to be accomplished [length has to be specified for the individual product]. The mucilaginous preparations may be consumed with or without the seeds.</p>

4.3. Contraindications

Well-established use	Traditional use
<p>Hypersensitivity to the active substance.</p> <p>Linseed should not be used by patients with a sudden change in bowel habit that persists for more than 2 weeks, undiagnosed rectal bleeding and failure to defaecate following the use of a laxative.</p> <p>Linseed should also not be used by patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and cardia or existing intestinal blockage (ileus), paralysis (ileus) of the intestine or megacolon.</p>	<p>Hypersensitivity to the active substance.</p> <p>This product should not be taken by patients, who have difficulty in swallowing or any throat problems.</p>

Well-established use	Traditional use
This product should not be taken by patients, who have difficulty swallowing or any throat problems.	

4.4. Special warnings and precautions for use

Well-established use	Traditional use
<p>The use is not recommended in children under 12 years due to insufficient data on safety and efficacy.</p> <p>If abdominal pain occurs or in cases of any irregularity of frequency of faeces, the use of linseed should be discontinued and medical advice must be sought.</p> <p>Taking this herbal substance without adequate fluid, may cause it to swell and block the throat or oesophagus and may cause choking. Intestinal obstruction may occur if adequate fluid intake is not maintained. If experiencing chest pain, vomiting, or difficulty in swallowing or breathing after taking this herbal substance, immediate medical attention should be sought.</p> <p>The treatment of debilitated patients and elderly should be supervised.</p> <p>Investigations in healthy women suggest that long term use of linseed may have an oestrogenic effect, and its use is therefore not recommended in women with hormonally dependent tumours.</p>	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>The treatment of debilitated patients and elderly should be supervised.</p> <p>Investigations in healthy women suggest that long term use of linseed may have an oestrogenic effect, and its use is therefore not recommended in women with hormonally dependent tumours.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
<p>Enteral absorption of concomitantly administered medicines may be delayed by bulk forming laxatives such as linseed.</p> <p>For this reason the product should be taken at least ½ to 1 hour before or after intake of other medicinal products.</p> <p>In order to decrease the risk of gastrointestinal obstruction (ileus), linseed should be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids, loperamide) only under medical supervision.</p>	<p>Enteral absorption of concomitantly administered medicines may be delayed by a demulcent preparation of linseed.</p> <p>For this reason the product should not be taken ½ to 1 hour before or after intake of other medicinal products.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
<p>There are no reports of any harmful or deleterious effects during pregnancy and lactation.</p> <p>Investigations in healthy women suggest that linseed may have an oestrogenic effect.</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>	<p>There are no reports of any harmful or deleterious effects during pregnancy and lactation.</p> <p>Investigations in healthy women suggest that linseed may have an oestrogenic effect.</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
<p>Not relevant.</p>	<p>Not relevant.</p>

4.8. Undesirable effects

Well-established use	Traditional use
<p>Meteorism, occurring with the use of the product, is common.</p> <p>Reactions of hypersensitivity including anaphylaxis-like reactions may occur very rarely.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.</p>	<p>Meteorism, occurring with the use of the product, is common.</p> <p>Reactions of hypersensitivity including anaphylaxis-like reactions may occur very rarely.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
<p>Overdose with linseed may cause abdominal discomfort, flatulence and possibly intestinal obstruction. Adequate fluid intake should be maintained and management should be symptomatic.</p>	<p>No case of overdose has been reported.</p>

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
<p>Pharmacotherapeutic group: Bulk Producers Proposed ATC code: A 06 AC</p> <p>The active ingredient linseed consists of the dried, ripe seeds of <i>Linum usitatissimum</i> L.</p> <p>The seeds contain nearly 25 % of bulk materials (3 - 6 % of mucilage, 4 - 7 % of alimentary fibres).</p> <p>The laxative effects of linseed have long been recognised 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 results in a decrease in transit time. The swollen mass of mucilage forms a lubrication layer facilitating the transit of intestinal content.</p> <p>Progress of action: Linseed usually acts within 12 to 24 hours. Sometimes the maximum effect is not reached before 2 or 3 days.</p> <p>Broken seeds do not always cause a stretch stimulus because the increase in volume may already start in the stomach. Whole or "bruised seeds" have a delayed increase in volume.</p> <p>The use in conditions, in which easy defaecation with soft stool is desirable, is scientifically substantiated on the basis of the laxative effects but there are no special data available.</p>	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</p>

5.2. Pharmacokinetic properties

Well-established use	Traditional use
<p>One part of the bulk materials in linseed is defaecated, the other part is fermented 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.</p>	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</p>

5.3. Preclinical safety data

Well-established use	Traditional use
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
Not applicable.	Not applicable.

7. Date of compilation/last revision

10 March 2015