European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 October 2005
Doc. Ref. EMEA/HMPC/340857/2005

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON ISPAGHULA HUSK (PLANTAGO OVATA, TEGUMENTUM)

DISCUSSION IN THE DRAFTING GROUP ON SAFETY & EFFICACY	May 2005 June 2005 September 2005
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	September 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 January 2006

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; well-established use.

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COMMUNITY HERBAL MONOGRAPH ON
ISPAGHULA HUSK (PLANTAGO OVATA, TEGUMENTUM)

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished products.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1]

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(1)(a)(ii) of Directive 2001/83/EC as amended Ispaghula husk[2] consists of the episperm and collapsed adjacent layers removed from the seeds of *Plantago ovata* Forssk. (*P. ispaghula* Roxb.)	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
Herbal substance or herbal preparation in solid dosage forms such as granules. The pharmaceutical form should be described according to the standard terms published by the European Pharmacopeia.	

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product a) for the treatment of habitual constipation; b) in conditions in which easy defaecation with soft stools is desirable, e.g. in cases of painful defaecation after rectal or anal surgery, anal fissures and haemorrhoids;	None

[1] The declaration of all active substances should be done in accordance with the 'Guideline on quality of herbal medicinal products / traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev.1, EMEA/CVMP/814/00 Rev.1).
[2] The herbal substance complies with the European Pharmacopoeia (monograph reference 01/2005:1334)

c) in patients to whom an increased daily fibre intake may be advisable e.g. as an adjuvant in constipation predominant irritable bowel syndrome, as an adjuvant to diet in hypercholesterolemia (see section 4.4 Special warnings and precautions for use and section 5.1 Pharmacodynamic properties)	

4.2 Posology and method of administration

Well-established use	Traditional use
Posology Oral use Indications a) and b) Daily dose *Adolescents over 12 years of age, adults, elderly* 7 - 11 g in 1 - 3 doses *Children from 6 to 12 years of age* Half to two-thirds of the adult dose (3 - 8 g) daily Indication c) *Adolescents over 12 years of age, adults, elderly* 7 - 20 g in 1 - 3 doses **Method of administration** Mix approximately 1 g of the herbal substance with at least 30 ml of water, milk, fruit juice or other liquid; stir briskly and swallow as quickly as possible. Alternatively the herbal substance can be taken and swallowed with sufficient quantity (at least 30 ml per g of herbal substance) of water, milk, fruit juice or other liquid; 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. Warning: not to be taken immediately prior to bed-time. **Duration of use** See section 4.4 Special warnings and precautions for use.	

4.3 Contraindications

Well-established use	Traditional use
Ispaghula husk is not to 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. Ispaghula husk is also not to be used by patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and cardia, potential or existing intestinal blockage (ileus), paralysis of the intestine or megacolon, diabetes mellitus, which is difficult to regulate. Patients with known hypersensitivity to Ispaghula husk should not use Ispaghula husk preparations.	

4.4 Special warnings and precautions for use

Well-established use	Traditional use
As there is no sufficient experience available, - use is not recommended in children below the age of 6 years for indications a) and b). Bulk producers should be used before using other purgatives if change of nutrition is not successful; - use is not recommended in children below the age of 12 years for indication c). Ispaghula husk 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 (ileus). Indication a) If the constipation does not resolve within 3 days or if abdominal pain occurs or in case of any irregularity of faeces, the use of Ispaghula husk should be discontinued and medical advice must be sought. Indication c) The use of Ispaghula husk as an adjuvant to diet in hypercholesterolemia requires medical supervision A sufficient amount of liquid should always be taken e.g. 30 ml of water per 1 g of herbal substance. In the package leaflet, the patient is informed about the following warning: **Warning** Take this product with at least 150 ml of water or other fluid. Taking this product without adequate fluid may cause it to swell and block your throat or oesophagus and may cause choking. Intestinal	

obstruction may occur should an adequate fluid intake not be maintained. Do not take this product if you have ever had difficulty in swallowing or have any throat problems. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention. The treatment of the debilitated patient requires medical supervision. The treatment of elderly patients should be supervised.	

4.5 Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
Enteral absorption of concomitantly administered medicines such as minerals (e.g. lithium), vitamins (B 12), cardiac glycosides, coumarin derivates, and carbamazepine may be delayed. For this reason the product should not be taken ½ to 1 hour before or after intake of other medicinal products. If the product is taken together with meals in the case of insulin dependent diabetics it may be necessary to reduce the insulin dose. Ispaghula husk should be used concomitantly with thyroid hormones only under medical supervision because the dose of the thyroid hormones may have to be adjusted. In order to decrease the risk of gastrointestinal obstruction (ileus) Ispaghula husk should only be used under medical supervision together with medicinal products known to inhibit the peristaltic movement (e.g. morphinomimetics, loperamide).	

4.6 Pregnancy and lactation

Well-established use	Traditional use
No restriction. Bulk producers should be used before using other purgatives if change of nutrition is not successful.	

4.7 Effects on ability to drive and use machines

Well-established use	Traditional use
Not known.	

4.8 Undesirable effects

Well-established use	Traditional use
Flatulence may occur with the use of the product, which generally disappears in the course of the treatment. Abdominal distension and risk of intestinal or oesophageal obstruction and faecal impaction, particularly if swallowed with insufficient fluid. Due to the allergic potential of Ispaghula, patients must be aware of reactions of hypersensitivity including anaphylaxis-like reactions very rarely.	

4.9 Overdose

Well-established use	Traditional use
Overdose with Ispaghula husk may cause abdominal discomfort and flatulence and even intestinal obstruction. An adequate fluid intake should be maintained and management should be symptomatic.	

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: Laxatives – Bulk Producers, other Cholesterol and Triglyceride Reducers ATC-code: A 06 AC, C 10 AX The active ingredient Ispaghula husk consists of the epidermis and adjacent layers of the dried, ripe seeds of *Plantago ovata* Forssk. Ispaghula husk is particularly rich in alimentary fibres and mucilages; with its content of mucilage being higher than other Plantago species. Ispaghula husk is capable of absorbing up to 40 times its own weight in water. Ispaghula husk consists 85 % water-soluble fiber, it is partly fermentable (in-vitro 72 % unfermentable residue) and acts by hydration in the bowel. The pharmacological effects, gut motility and transit rate can be modified by Ispaghula husk through mechanical stimulation of the gut wall depending on the increase in intestinal bulk by water and the decrease in viscosity of the luminal contents. When taken with a sufficient amount of liquid (at least 30 ml per 1 g of herbal substance) Ispaghula husk produces an increased volume of intestinal contents due to its highly bulking properties and	Not applicable as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

hence a stretch stimulus which triggers defaecation; at the same time the swollen mass of mucilage forms a lubricating layer which makes the transit of intestinal contents easier. In mild to moderate hypercholesterolemia a reduction of serum cholesterol of approximately 5 % is reported in literature. Investigations which study the effect of a decrease in cardiovascular disease and in total mortality are not available.	

5.2 Pharmacokinetic properties

Well-established use	Traditional use
Absorption: The material hydrates and swells to form a mucilage because it is only partially solubilised. Less than 10 % of the mucilage gets hydolysed in the stomach; mainly free arabinose is well absorbed. *Progress of action*: Ispaghula husk usually acts within 12 to 24 hours after single administration. Sometimes the maximum effect is not reached for 2 or 3 days. *Elimination*: human intestinal flora in the large intestine degrades the polysaccharides.	Not applicable as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Well-established use	Traditional use
No new data available. No data are available in the literature on mutagenicity and carcinogenicity. Data are based on scientific literature about *Plantaginis ovatae testa*; there are no preclinical concerns based on extensive human experience.	Not applicable as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

6. DATE OF COMPILATION

20 September 2005