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 ISPAGHULA SEED

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.eu.int http://www.emea.eu.int

**Final Proposal for a core-data for Ispaghula Seed (*Plantago ovata semen* Forsk)**

The Working Party on Herbal Medicinal Products proposes the following core-data for Ispaghula Seed (March 2003).

## 1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ispaghula seeds[1]

## 3. PHARMACEUTICAL FORM

Herbal drug or herbal drug preparation in solid dosage forms such as granules.
The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications[2]

Herbal medicinal product
a) for the treatment of habitual constipation;

b) in conditions in which easy defecation with soft stools is desirable, e.g. in cases of painful defecation after rectal or anal surgery, anal fissures or haemorrhoids.

### 4.2 Posology and method of administration

Daily dose:
Adolescents over 12 years of age, adults, elderly: 12 - 40 g in 1 - 3 doses.

Method of administration: Mix approximately 1 g of drug with at least 30 ml of water, milk, fruit juice or other liquid; stir briskly and swallow as quickly as possible. Alternatively the drug can be taken and swallowed with sufficient quantity (at least 30 ml per g of drug) 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:
No restriction

### 4.3 Contraindications

[1] The herbal drug complies with the European Pharmacopoeia
[2] Consensus achieved on the indications under the criteria defined in the Points to consider on the evidence of safety and efficacy required for well established herbal medicinal products in bibliographical applications (HMPWP/23/99)

Ispaghula seed is not to be used by patients with faecal impaction and undiagnosed abdominal symptoms, abdominal pain, nausea and vomiting unless advised by a doctor, 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.
Ispaghula seed is also not to be used by patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the esophagus and cardia, potential or existing intestinal blockage (ileus), or megacolon, diabetes mellitus, which is difficult to regulate. Ispaghula seed is finally not to be used by patients with known hypersensitivity to ispaghula or any of the other constituents of the product.

## 4.4 Special warning and precautions for use

A sufficient amount of liquid should always be taken e.g. 30 ml of water per 1 g of drug.

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 esophagus 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 should be supervised.

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

If symptoms worsen or persist, a physician should be consulted.

## 4.5 Interaction with other medicinal products and other forms of interaction

Enteral absorption of concomitantly administered medicines such as minerals (e. g. calcium, iron, lithium, zinc), vitamins (B12), cardiac glycosides and coumarin derivates may be delayed. For this reason the product should not be taken ½ to 1 hour before or after intake of other drugs.
In the case of insulin dependent diabetics it may be necessary to reduce the insulin dose.

## 4.6 Pregnancy and lactation

No restriction.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

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 fecal impaction, particularly if swallowed with insufficient fluid.
Due to occupational exposure, risk of allergic reaction possible through inhalation of the powder. Due to the allergic potential of ispaghula, patients must be aware of reactions of hypersensitivity including anaphylaxis-like reactions in single cases.

## 4.9 Overdose

Overdose with ispaghula seed 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

Pharmacotherapeutic group: Laxatives – Bulk Producers
ATC-Code: A 06 AC

The active ingedient ispaghula seed consists of the dried, ripe seeds of *Plantago ovata* Forsk. Ispaghula seed is particularly rich in alimentary fibres and mucilages. Ispaghula seed is capable of absorbing up to 10 times its own weight in water. Ispaghula seed consists of 85 % water-soluble fiber, it is partly fermentable (in vitro 72 % unfermentable residue) and act by hydration in the bowel. The pharmacological effects, gut motility and transit rate can be modified by ispaghula through mechanical stimulation of the gut wall depending on the increase in intestinal bulk by water and in viscosity of the luminal contents or by contact with rough fiber particles. When taken with a sufficient amount of liquid (at least 30 ml per 1 g of drug) ispaghula produces an increased volume of intestinal contents due to it's highly bulking properties and hence a stretch stimulus which triggers defacation; at the same time the swollen mass of mucilage forms a lubricating layer which makes the transit of intestinal contents easier.
Level of evidence:
indication a): IV
indication b): IV

### 5.2 Pharmacokinetic properties

*Absorption*: The material hydrates and swells to form a mucilage because it is only partially solubilised. Less than 10 % of the mucilage gets hydrolysed in the stomach; mainly free arabinose is well absorbed.

*Progress of action*: Ispaghula seed 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.

### 5.3 Preclinical safety data

No new experimental data available.
No data are available in the literature on mutagenicity and carcinogenicity.
Data are based on scientific literature about *Plantaginis ovatae semen*; there are no preclinical concerns based on extensive human experience.

## 6 Date of compilation