



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 HUSK

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Final proposal for a core data for Ispaghula Husk (*Plantago ovata testa* Forsk)

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

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ispaghula husk¹

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 indications²

Herbal medicinal product

- a) for the treatment of habitual constipation;
- b) as adjuvant in the symptomatic treatment of diarrhoea from various causes (see also section 4.4 Special warnings and precautions for use);
- c) 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 and haemorrhoids;
- d) in conditions which need an increased daily fibre intake e.g. as an adjuvant in irritable bowel syndrome, as an adjuvant to diet in hypercholesterolemia (see section 5.1 Pharmacological properties).

4.2 Posology and method of administration

Daily dose:

Adolescents over 12 years of age, adults, elderly:

7 - 11 g in 1 - 3 doses : for indications a) and c)

7 - 20 g in 1 - 3 doses : for indication b) and d)

¹ The herbal drug complies with the European Pharmacopoeia

² It is very unlikely that a product will have all indications in one package leaflet, because the package size will not fit all indications.

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:

See section 4.4 Special warnings and precautions for use

4.3 Contraindications

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, 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 husk 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 husk 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 warnings 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 patients should be supervised.

In case of diarrhoea sufficient intake of water and electrolytes is important.

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

Indication b)

Medical advice should be sought if the symptoms persist more than 3 days in order to make a definitive diagnosis as to the cause of diarrhoea.

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

If the product is taken together with meals 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 faecal 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 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

Pharmacotherapeutic group: Laxatives – Bulk Producers, other Antidiarrhoeals

ATC code: A 06 AC, A 07 X

The active ingredient ispaghula husk consists of the epidermis and adjacent layers of the dried, ripe seeds of *Plantago ovata* Forsk. 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 of 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 in viscosity of the luminal contents. When taken with a sufficient amount of liquid (at least 30 ml per 1 g of drug) ispaghula husk produces an increased volume of intestinal contents due to its highly bulking properties and 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.

Level of evidence:

indication a): level I

indication b): level IV

indication c): level I

indication d): level I

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 husk usually acts within 12 to 24 hours after single administration. Sometimes the maximum effect is not reached for two or three 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 testa*; there are no preclinical concerns based on extensive human experience.

6 Date of compilation