SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Manx Ispaghula Husk Granules Orange for Oral Suspension 3.5g

Ispaghula Husk Granules for Oral Suspension 3.5g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains Ispaghula husk 3.5g

Excipients with known effect

Each sachet contains 0.06g of aspartame

Each sachet contains 0.009g sucrose

See Section 4.4. Special warnings and precautions for use.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules for oral suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Used for the treatment of habitual constipation; conditions in which easy defecation with soft stools is desirable, for example, in cases of anal fissures, haemorrhoids, after rectal or anal surgery as well as in pregnancy; adjuvant symptomatic therapy in cases of diarrhoea from various causes; conditions which need an increased daily fibre intake, for example, irritable bowel syndrome.

4.2 Posology and method of administration

For oral use only

Adults, elderly, children over 12 years of age: one sachet up to three times a day as needed.

Additional doses up to a maximum of 5 sachets can be used if required.

Maximum daily dose = 5 sachets

Method of administration: Mix one sachet in 150ml (¼ pint) cool water, stir briskly and swallow as quickly as possible. Then maintain adequate fluid intake.

The product should be taken during the day at least ½ to 1 hour before or after intake of food or other medicines.

Warning: not to be taken immediately prior to going to bed.

The effect starts 12 -14 hours later.

When preparing the product for administration, it is important to try to avoid inhaling any of

the powder in order to minimise the risk of sensitisation to the active ingredient.

Duration of administration: 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 constipation.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 (See Section 4.4 Special warnings and precautions for use).

Patients with a sudden change in bowel habit that has persisted more than two weeks.

Undiagnosed rectal bleeding and failure to defecate following the use of a laxative.

Ispaghula husk is contraindicated in patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and

cardia, intestinal obstruction, faecal impaction, natural or drug-induced reduction of gut motility and colonic atony such as senile mega-colon.

Patients who have difficulty in swallowing or any throat problems.

Product not to be used by children aged less than 12 years.

4.4 Special warnings and precautions for use

The product should not be taken dry and should always be taken mixed with fluid (150ml of water or other liquid per sachet).

Ispaghula husk should not be used by patients with faecal impaction and symptoms such as abdominal pain, nausea and vomiting unless advised by a doctor because these symptoms can be signs of potential or existing intestinal blockage (ileus).

If abdominal pain occurs or in cases of any irregularity of faeces, the use of ispaghula husk should be discontinued and medical advice must be sought.

When taken with inadequate fluid amounts, bulk forming agents can cause obstruction of the throat and oesophagus with choking and intestinal obstruction. Symptoms can be chest pain, vomiting, or difficulty in swallowing or breathing.

The treatment of debilitated patients and / or elderly patients requires medical supervision.

In order to decrease the risk of gastrointestinal obstruction ispaghula husk should not be used together with medicinal products known to inhibit peristaltic movement (eg opioids) unless under medical supervision.

The last dose should not be taken immediately before going to sleep since impaired or reduced gastric motility may impair the intestinal passage and then cause sub-obstruction.

If symptoms persist longer than 3 days, the patient should consult a doctor or healthcare professional.

Warning on hypersensitivity reactions: In individuals with continued occupational contact to powder of Plantago ovata seeds (ie healthcare workers, caregivers) allergic sensitization may occur due to inhalation, this is more frequent in atopic individuals. This sensitization usually leads to hypersensitivity reactions which could be serious (see 4.8 Undesirable effects).

It is recommended to assess clinically the possible sensitisation of individuals at risk and, if justified, to perform specific diagnostic tests.

In case of proven sensitisation leading to hypersensitivity reactions, exposure to the product should be stopped immediately and avoided in the future (see 4.3 Contraindications).

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Due to its aspartame content, ispaghula husk should not be given to patients with phenylketonuria. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Paediatric Population

Use is not recommended in children below 12 years of age due to insufficient data on safety and efficacy. Laxative bulk producers should be used before using other purgatives if change of nutrition is not successful.

4.5 Interaction with other medicinal products and other forms of interaction

Enteral absorption of concomitantly administered medicines such as minerals, vitamins (B12), cardiac glycosides, coumarin derivatives, carbamazepine and lithium may be delayed. For this reason the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

Diabetic patients should take ispaghula husk only under medical supervision because adjustment of anti-diabetic therapy may be necessary.

Use of ispaghula husk concomitantly with thyroid hormones requires medical supervision because the dose of the thyroid hormones may have to be adjusted.

In order to decrease the risk of gastrointestinal obstruction ispaghula husk should not be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids) unless under medical supervision.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are limited amount of data (less than 300 pregnancy outcomes) from the use of ispaghula husk in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3 Preclinical safety data).

Lactation

The use of ispaghula husk may be considered during pregnancy and lactation, if necessary, and if change of nutrition is not successful. Laxative bulk producers should be used before using other purgatives.

Fertility

There is no evidence of an effect on the fertility in the rat following oral application (see Section 5.3 'Preclinical safety data').

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Special attention should be given to individuals manipulating the powder formulations routinely (see 4.4 Special warnings and precautions for use).

Adverse events which have been associated with ispaghula husk are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity disorders[1,2]
Eye Disorders	Not known	Conjunctivitis[2]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Rhinitis[2]
Gastrointestinal Disorders	Not known	Flatulence, abdominal distension, intestinal obstruction, oesophageal obstruction, faecal impaction[3]
Skin and Subcutaneous Tissue Disorders	Not known	Skin rash[2]

Description of Selected Adverse Reactions

[1] Including rash, anaphylaxis, pruritus, and bronchospasm

[2] Ispaghula/psyllium husk contains potent allergens. The exposure to these allergens is possible through oral administration, contact with the skin and, in the case of powder formulations, also by inhalation. As a consequence to this allergic potential, individuals exposed to the product can develop hypersensitivity reactions such as rhinitis, conjunctivitis, bronchospasm and in some cases, anaphylaxis. Cutaneous symptoms such as exanthema and/or pruritus have also been reported.

[3] A small amount of flatulence may sometimes occur during the first few days of treatment, but should diminish during continued treatment. Abdominal distension and risk of intestinal or oesophageal obstruction and faecal impaction may occur, particularly if swallowed with insufficient fluid.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

4.9 Overdose

Symptoms

Overdose with ispaghula husk may cause abdominal discomfort, flatulence, and intestinal obstruction.

Management

Adequate fluid intake should be maintained, particularly if the granules have been taken without water, contrary to administration instructions and management should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Bulk-forming laxatives, ATC Code: A06AC01

The active ingredient ispaghula husk consists of the episperm and collapsed adjacent layers removed from the seeds of *Plantago ovata* FORSSK (Plantago ispaghula Roxb.). Ispaghula husk is particularly rich in alimentary fibres and mucilages; its mucilage content being higher than that of 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 fibre; it is partly fermentable (in vitro 72% unfermentable residue) and act by hydration in the bowel.

Gut motility and transit rate can be modified by ispaghula husk through mechanical stimulation of the gut wall as a result of the increase in intestinal bulk by water and the decrease in viscosity of the luminal contents or by contact with rough fibre particles. When taken with a sufficient amount of liquid (at least 30ml per 1g of herbal substance), ispaghula husk produces an increased volume of intestinal contents due to its highly bulking properties and hence a stretch stimulus which triggers defecation; at the same time the swollen mass of mucilage forms a lubricating layer which makes the transit of intestinal contents easier.

Progress of action: ispaghula husk usually acts within 12 to 24 hours after single administration. Sometimes the maximum effect is reached after 2 to 3 days.

5.2 Pharmacokinetic properties

The material hydrates and swells to form amucilage because it is only partially solubilised. Polysaccharides, such as those which dietary fibres are made of, must be hydrolysed to monosaccharides before intestinal uptake can occur. The sugar residues of the xylan backbone and the side chains are joined by ß-linkages, which cannot be broken by human digestive enzymes.

Less than 10% of the mucilage gets hydrolysed in the stomach, with formation of free arabinose. Intestinal absorption of the free arabinose is approximately 85% to 93%.

To varying degrees, dietary fibre is fermented by bacteria in the colon, resulting in production of carbon dioxide, hydrogen, methane, water, and short-chain fatty acids, which are absorbed and brought into the hepatic circulation. In humans, such fibre reaches the large bowel in a highly polymerised form that is fermented to a limited extent, resulting in increased faecal concentration and excretion of short-chain fatty acids.

5.3 Preclinical safety data

Ispaghula husk was fed to rats at levels high as 10% of the diet for periods up to 13 weeks (three 28-day studies, one 13-week study). The consumption ranged from

3,876 to 11,809 mg/kg/day (3-16 times of the human dosage calculated for a 60 kg human). Effects seen were lower serum total protein, albumin, globulin, total iron-binding capacity, calcium, potassium, and cholesterol; and higher aspartate transaminase and alanine transaminase activities relative to control. The absence of any increases in urinary protein and any differences in growth or feed efficiency in ispaghula husk fed rats may give evidence that there are no adverse effects on protein metabolism. Because the absorption of ispaghula husk is very limited, histopathological evaluations were limited to the gastrointestinal tract, liver, kidneys and gross lesions without observing any treatment-related effect.

In a study on fertility, embryo-foetal development, and pre- and postnatal development (multigeneration study) ispaghula husk (0, 1, 2.5, or 5% (w/w) of the diet) was administered to rats continuously through two generations. For fertility and foetal development and teratogenesis the no-observed-adverse-effects-limit (NOAEL) was 5% of the diet, while for offspring growth and development the NOAEL was given with 1% of the diet based on reductions in pup weights.

The study on embryo-foetal development in rabbits (ispaghula husk as 0, 2.5, 5 or 10% (w/w) of diet) has to be considered as preliminary. Conclusions cannot be drawn.

Adequate tests on reproductive toxicity, genotoxicity, and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Natural orange flavour (maltodextrin, acacia gum, natural tocopherol extracts), aspartame, beta-carotene (maltodextrin, acacia [E414], hydrogentated vegetable oil, sucrose, beta-carotene [E 160a], sodium ascorbate [E 1301], dl-α-tocopherol [E 307]), citric acid monohydrate and pregelatinised starch.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Sachet containing 4.16 g. Sachets (white paper outer, then polyethylene, then aluminium, then polyethylene) are packed in boxes of 7, 10, 30 or 60.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 11311/0793

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 August 2003 / 26 March 2009

10 DATE OF REVISION OF THE TEXT

04/07/2025