

Essential Information: Fybogel Hi-Fibre Orange PL 00063/0064

Active Ingredients: A sachet contains 3.5g ispaghula husk EP.

Indications: For the treatment of patients requiring a high fibre regimen: for example, for the relief of constipation, including constipation in pregnancy and the maintenance of regularity; for the management of bowel function in patients with haemorrhoids.

Dosage and Administration: If there have been no bowel movements after 3 days of treatment a doctor or healthcare professional should be consulted. (See section 4.4 'Special warnings and precautions for use')

Posology: Adults: One sachet, morning and evening Elderly: There is no indication that dosage needs to be modified for the elderly. Paediatric Population: Children over 12 years: One sachet, morning and evening. Children aged 6 to 12 years: Half to one level 5 ml spoonful, depending on age and size, morning and evening. Children under 6 years: The use in children under 6 years of age is not recommended (See section 4.4 'Special warnings and precautions for use'). The effects start 12-24 hours later.

Method of Administration

- The medicine is intended for oral use as a suspension in a full drink of water (See section 4.4). The granules should be stirred into a glass of water and taken as soon as possible, preferably after meals.
- The product should be taken during the day at least ½ to 1 hour before or after intake of other medicines and should not be taken immediately before going to sleep.
- When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimize the risk of sensitisation to the active ingredient.

Contraindications: Hypersensitivity to ispaghula husk 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. This medicine is contra-indicated 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.

Special warnings and precautions for use:

- The product should not be taken dry and should always be taken mixed with fluid (5 fluid ounces or 150 mL 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 psyllium seed 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 (e.g. opioids) and then only 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.
- This medicine contains 16mg aspartame in each sachet.
- 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.
- This medicine contains less than 1 mmol sodium (23 mg) in each sachet, that is to say essentially 'sodium-free'.
- This medicine contains 0.25 mmol (or 9.76 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- 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 (i.e. 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 sensitization 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).
- Paediatric Population: Use is not recommended in children below 6 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.

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).

• Breast-feeding: 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: No known effects.

Side 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 ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ 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 and abdominal distension 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.

Legal Classification:GSL

Licence Holder:

Reckitt Benckiser Healthcare (UK) Limited
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 Hull
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Price: £3.99 (10s); £8.99 (30s).

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) Ltd on: 0333 200 5345