Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fybogel Mebeverine Granules for Oral Suspension Ispaghula Husk 3.5g Mebeverine Hydrochloride 135mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active ingredient	g/Sachet
Ispaghula husk	3.5
Mebeverine hydrochloride	0.135

Excipient(s) with known effect:

Aspartame: 16 mg per sachet

Sodium: 58.65 mg (2.55 mmol) per sachet

Total maximum daily dose (MDD) is 176.0mg (7.65mmol)

Potassium: 97.6 mg (2.5 mmol) per sachet

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral suspension in a unit dose sachet
Buff-coloured granules and orange-coloured spheroids.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of irritable bowel syndrome.

4.2 Posology and method of administration

A doctor should be consulted if you develop new symptoms, or if your symptoms worsen, or if symptoms do not improve after 2 weeks treatment (See section 4.4).

Posology

Adults and children over 12: One sachet morning and evening, taken half an hour before meals. A third dose may be taken before the midday meal if necessary.

Elderly**:** There is no indication that the dose needs to be modified for the elderly.

Paediatric Population
Children below 12: The product is not recommended in children under 12 years of age (see Section 4.4).

Method of Administration
The product is intended for oral administration as a suspension in water (See section 4.4 Special Warnings and Precautions for Use). The product should be stirred into a glass of cold water (approx. 240 mls) and taken immediately.

The product should be taken during the day at least ½ to 1 hour before or after intake of other medicines and the product should not be taken immediately before going to sleep.

Effects may take several hours.

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.

4.3 Contraindications

Patients suffering from abnormal constrictions in the gastrointestinal tract, with diseases of the oesophagus and cardia, intestinal obstruction, faecal impaction, natural or drug-induced reduction of gut motility, paralytic ileus and colonic atony such as senile megacolon.

Hypersensitivity to ispaghula husk or mebeverine (see 4.4 Special warnings and precautions for use)or to any of the excipients listed in section 6.1.
Patients with a sudden change in bowel habit that has persisted more than two weeks.

Undiagnosed rectal bleeding following the use of a laxative.

Failure to defecate following the use of a laxative.

Patients who have difficulty in swallowing or any throat problems.

4.4 Special warnings and precautions for use

Change of diet should always be considered before pharmacological management of irritable bowel syndrome. It is recommended that the use of a bulk laxative alone should be tried before using this bulk laxative/antispasmodic combined product.

Mebeverine should be used with care in patients with hepatic or renal impairment, and those with cardiac disorders such as heart block.

Not recommended for children under 12.

Fybogel Mebeverine should not be taken in the dry form and should always be taken mixed with fluid (8 fluid ounces or 240 mL of water or other liquid per sachet). Gastrointestinal obstruction or impaction have been reported with hydrophilic mucilloid preparations when taken with insufficient liquid, contrary to administration instructions.

Adequate fluid intake should be maintained.
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.

Ispaghula husk should not be used by patients with 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.

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.

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

In order to decrease the risk of gastrointestinal obstruction ispaghula husk should be used with caution with medicinal products known to inhibit peristaltic movement (e.g. opioids) and only under medical supervision (see section 4.5).

This 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.

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks of treatment.

Warning on hypersensitivity reactions: In individuals with continued occupational contact to powder of ispaghula husk (e.g. healthcare workers and caregivers) allergic sensitisation may occur due to inhalation; this is more frequent in atopic individuals. This sensitisation usually leads to hypersensitivity reactions which could be serious (See 4.8).

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).

This medicine contains 2.5 mmol (or 97.6 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicinal product contains 58.65 mg sodium per sachet, equivalent to 2.9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 16 mg 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.
Due to its aspartame content Fybogel Mebeverine should not be given to patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

Ispaghula and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other drugs such as cardiac glycosides, coumarin derivatives, lithium, carbamazepine or vitamins (such as vitamin B12) and minerals (such as calcium, iron, or zinc). For this reason the product should 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 only be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids, opioid-like agents and loperamide) if under medical supervision (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy:
The product should not be used during pregnancy unless considered essential by the physician.
There are limited 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).
There are no or limited amounts of data from the use of mebeverine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Breast-feeding:
This product should not be used in breast-feeding.
Mebeverine is excreted in human milk. The excretion of mebeverine in milk has not been studied in animals.
No effects of ispaghula husk have been shown in breast-fed newborns/infants of treated mothers.

Fertility:
There is no evidence of an effect on fertility in the rat following oral application (see section 5.3). There are no clinical data on male or female fertility.

4.7 Effects on ability to drive and use machines

The product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with ispaghula husk and mebeverine hydrochloride at OTC doses, in short term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

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 or mebeverine 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[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 impaction3
Skin and Subcutaneous Tissue Disorders	Not known	Skin rash[2]

Description of Selected Adverse Reactions
[1] Including rash, urticaria, anaphylaxis, pruritus, angioedema, 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. Special attention should be given to individuals manipulating the powder formulations routinely (see section 4.4).
[3] Flatulence and bloating may be experienced 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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Symptoms:
The patient may notice abdominal discomfort and flatulence and intestinal obstruction.
Mebeverine can have neurological or cardiovascular effects in overdose.
Management:
In the event of overdosage conservative measures should be taken. Attention should be paid to maintaining an adequate fluid intake, particularly if the product has been taken without water contrary to the administration instructions. Management should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Alimentary tract and metabolism; Drugs for constipation; Bulk-forming laxatives; Ispaghula, combinations.
ATC Code: A06AC51
Ispaghula husk

The active ingredient ispaghula husk consists of the episperm and collapsed adjacent layers removed from the seeds of Plantago ovate 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 absorping up to forty times its own weight of water in vitroand part of its activity can be attributed to its action as a simple bulking agent.

Ispaghula husk consists of 85% water-soluble fibre; it is partly fermentable (*in vitro* 72% unfermentable residue) and acts 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. 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 hence a stretch stimulus, which triggers defecation; at the same time the swollen mass of mucilage forms a lubricating layer, which makes transit of intestinal contents easier.

Progress of action: Ispaghula husk ususally acts as a laxative within 12 to 24 hours after single administration. Sometimes the maximum effect is reached after 2 to 3 days.

In addition, colonic bacteria are believed to use the hydrated material as a metabolic substrate. This results in an increase in the bacterial cell mass with a consequential softening of the faeces.

Mebeverine hydrochloride

Mebeverine hydrochloride is a musculotropic antispasmodic agent which exerts a direct action on the smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. It is rapidly absorbed with peak concentrations achieved between 1-3 hours after ingestion.

5.2 Pharmacokinetic properties

Ispaghula husk

Ispaghula husk has a physical mode of action and does not depend upon absorption into the gastrointestinal tract.

The material hydrates and swells to form a mucilage 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 β-linkages, which cannot be broken by human digestive enzymes.

Less than 10% of 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.

Mebeverine hydrochloride

Mebeverine hydrochloride has been shown to be nearly completely absorbed following oral administration, but first-pass metabolism is extensive and plasma levels of unchanged drug are very low. This supports the view that its action is directly on the muscle of the gastrointestinal tract, rather than as a result of systemic absorption.

Mebeverine hydrochloride is mainly metabolised by esterases, initially splitting the ester bonds into veratric acid and mebeverine alcohol, which are excreted in the urine.

5.3 Preclinical safety data

Ispaghula husk and mebeverine hydrochloride are well-established drug substances with a known safety record.

Ispaghula husk:

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 (multigenerational 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 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.

Tests on genotoxicity and carcinogenicity have not been performed.

Mebeverine hydrochloride:

There is no indication of teratogenic potential in rats and rabbits exposed to mebeverine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid
Potassium Hydrogen Carbonate
Sodium Hydrogen Carbonate
Orange flavour
Aspartame (E951)
Saccharin Sodium
Beta Carotene (E160a) 10% CWS/S
Contains: Beta Carotene
All-*rac*-α-Tocopherol
Maize oil refined
Maize Starch
Modified food starch
Polysorbate 80
Silica, Colloidal Anhydrous
Riboflavine Sodium Phosphate
Microcrystalline cellulose
Basic Butylated Methacrylate Copolymer
Sterilised Talc
Macrogol
Apocarotenal

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Store below 30ºC. Store in the original package.

6.5 Nature and contents of container

Sachets of paper/aluminium foil/polythene laminate enclosed in a cardboard outer.

Cartons containing 2 and 10 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

See Section 4.2.

The contents of one sachet should be stirred into a glass of cold water (240mls) and taken immediately.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/010/001

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10 DATE OF REVISION OF THE TEXT

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