Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fybogel Citrus 3.5 g Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose sachet contains 3.5 g ispaghula husk.

Excipient(s) with known effect:
Aspartame (E 951): 16 mg per sachet
Sodium: 6.95 mg (0.302 mmol) per sachet
Total maximum daily dose (MDD) is 13.9 mg (0.604 mmol)
Potassium: 9.76 mg (0.25 mmol) per sachet
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules
Semi-transparent buff coloured granules with an odour of orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In the management of patients requiring a high-fibre regimen.

4.2 Posology and method of administration

If there have been no bowel movements after 3 days of treatment a doctor should be consulted. (See section 4.4).

Posology
Adults and children over 12 years: One sachet or two 5 ml spoonfuls of granules to be reconstituted as directed each morning and evening, preferably after meals.

Elderly: There is no indication that dosage need be modified for the elderly.

Paediatric Population
Children 6 to 12 years: Half to one level 5 ml spoonful of granules, depending on age and size, to be reconstituted 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').

Method of administration

Fybogel Citrus is intended for oral use after suspension in water. The granules should be stirred into a glass of water and taken as soon as the effervescence subsides. Concentrated fruit juices or natural juice may be added to taste.

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.

The effects start 12-24 hours later.

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

Hypersensitivity to the active substance ispaghula husk, or to any of the excipients listed in section 6.1 (see 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.

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.

4.4 Special warnings and precautions for use

Use is not recommended in children below 6 years of age due to insufficient data on efficacy. Laxative bulk producers should be used before using other purgatives if change of nutrition is not successful.

The product should not be taken dry and should always be taken mixed with fluid (8 fluid ounces or 240mL 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.

If abdominal pain occurs or in cases of any irregularity of faeces, the use of ispaghula husk should be discontinued and medical advice should 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 be used with caution with medicinal products known to inhibit peristaltic movement (e.g. opioids) and then 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.

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

Warning on hypersensitivity reactions: In individuals with continued occupational contact to powder of ispaghula husk (i.e. healthcare workers, 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 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).

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.
Due to its aspartame content Fybogel Citrus should not be given to patients with phenylketonuria.

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.

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 know 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:
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 Preclinical safety data).
Patients should consult a doctor or pharmacist before taking Fybogel Citrus during pregnancy.

Breastfeeding:
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). No data are available regarding the effects on human fertility.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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

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.

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

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 impaction[3]
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, intestinal obstruction and flatulence.

Management:

In the event of overdosage, conservative measures should be taken. Attention should be paid to maintaining an adequate fluid intake, particularly if the granules have been taken without water contrary to administration instructions. Management should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Ispaghula (Psylla seeds); **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 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 defaecation; at the same time the swollen mass of mucilage forms a lubricating layer, which make 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 mode of action of Fybogel Citrusis physical and does not depend on absorption into the systemic circulation.

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 update 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 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 related 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 evaluation 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 post natal 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 NOAEL was 5% of the diet, while the 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous
Potassium hydrogen carbonate
Sodium hydrogen carbonate
Orange flavour
Aspartame (E951)
Beta Carotene (E160a) 10% CWS/S
contains:
Beta Carotene, all-*rac*-α-Tocopherol, Maize oil refined, Maize Starch and Modified food starch
Riboflavin Sodium Phosphate
Saccharin Sodium
Polysorbate 80
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30°C.
Sachets: Store in the original package to protect from moisture

6.5 Nature and contents of container

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

Carton containing 2, 10 or 30 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

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/009/001

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10 DATE OF REVISION OF THE TEXT

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