# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Fybogel Orange 3.5 g granules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose sachet contains 3.5g ispaghula husk.

Excipient(s) with known effect:
Aspartame (E 951): 16 mg per sachet
Sodium: 7.015 mg (0.305 mmol) per sachet
Total maximum daily dose (MDD) is 14.03 mg (0.610 mmol)
Potassium: 9.76 mg (0.25 mmol) per sachet
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Granules

Orange flavoured flaky granules of orange to buff colour which after dispersion in water form a suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For ahigh-fibre regime indicated for use in the relief of constipation.

### 4.2 Posology and method of administration

Fybogel Orange is intended for oral administration as a suspension in a full glass of water (See section 4.4). The granules should be stirred into a glass of water and taken as soon as possible. Concentrated fruit juices or natural juice may be added to taste.

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

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

Children aged 6 to 12 years: Half to one level 5 ml spoonful of granules, depending on age and size, to be reconstituted as above, morning and evening.

Children under 6 years: The use in children under 6 years of age is not recommended (See section 4.4 'Special warning and precautions for use').

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

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, 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**

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

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).

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 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 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 not be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids) and then only under medical supervision.

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 Plantago ovata seeds (e.g. 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

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 interactions**

Ispagula and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other drugs such as cardiac glycosides, coumarin derivatives, lithium, or vitamins (such as vitamin B12) and minerals (such as calcium, iron, or zinc). 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 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.

**4.6 Fertility, pregnancy and lactation**

Pregnancy: There are no data from the use of psyllium seed, and 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)

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

Patients should consult a doctor or pharmacist before taking Fybogel Orange during pregnancy.

Breast-feeding: The use of ispaghula husk may be considered during lactation, if necessary and if change of nutrition is not successful

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**

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 reactions with pruritus, bronchospasm and anaphylaxis[1] |
| Eye disorders | Not known | Conjunctivitis[1] |
| Respiratory, thoracic and mediastinal disorders | Not known | Rhinitis[1] |
| Gastrointestinal disorders | Not known | Flatulence, abdominal distension, intestinal obstruction, oesophageal obstruction, faecal impaction[2] |
| Skin and subcutaneous tissue disorders | Not known | Skin rash[1] |

Description of Selected Adverse Reactions

[1]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.

[2]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 Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

**4.9 Overdose**

In the event of overdosage conservative measures should be taken. The patient may notice abdominal discomfort and flatulence and intestinal obstruction. Adequate fluid intake should be maintained and management should be symptomatic, particularly if the granules have been taken without water contrary to administration instructions.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

**Pharmacotherapeutic Group:** Ispaghula Husk (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 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 as a laxative 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 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 relative to control. The absence of any increases in urinary protein and any differences in growth or feed efficacy in ispaghula husk fed to 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, embro-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 are carcinogencity 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
Modified food starch
Riboflavin Sodium Phosphate
Saccharin Sodium
Polysorbate 80
Colloidal anhydrous silica

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store below 30ºC.
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 10 or 30 sachets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

See section 4.2.

## 7 MARKETING AUTHORISATION HOLDER

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

**8 MARKETING AUTHORISATION NUMBER**

PA0979/009/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 8th April 1993
Date of last renewal: 8th April 2008

**10 DATE OF REVISION OF THE TEXT**

January 2021