SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fybogel Lemon.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

A sachet contains 3.5 g ispaghula husk EP.
Excipients with known effect:

Aspartame (E 951) 16 mg/sachet
Potassium 9.76 mg/Sachet

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Clinical Indication: 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 colostomy, ileostomy, haemorrhoids, anal fissure, chronic diarrhoea associated with diverticular disease, irritable bowel syndrome and ulcerative colitis.

4.2. Posology and Method of Administration

If there have been no bowel movements after three 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 size and age, 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

Fybogel Lemon 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, 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.

4.3. Contra-Indications

Hypersensitivity to ispaghula husk or to any of the excipients listed in 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.

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 Special 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 (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).

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.

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.

4.6. 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

4.7. Effects on Ability to Drive and Use Machines

Fybogel Lemon has no or negligible influence on the ability to drive and use machines.

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 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.

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: http://www.mhra.gov.uk/yellowcard.

4.9. Overdose

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

Management
And attention should be paid to maintaining an adequate fluid intake and management should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic Group: Ispaghula (Psyllia Seeds); **ATC Code:** A06AC01 Bulk producer

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, ts 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 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 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. Pre-clinical Safety Data

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.
The non-clinical data on toxicology of ispaghula husk preparations are incomplete, but available data indicate no signals of toxicological concern. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6.1 List of excipients

Potassium bicarbonate	Ph Eur
Sodium bicarbonate	Ph Eur
Citric acid	Ph Eur
Riboflavine sodium phosphate	Ph Eur
Aspartame	Ph Eur
Lemon flavour no. 1	HSE
Lemon flavour no. 4	HSE
Saccharin Sodium	Ph Eur
Polysorbate 80	Ph Eur
Silica colloidal anhydrous	Ph Eur

6.2. Incompatibilities

None known.

6.3. Shelf-Life

Three years.

6.4. Special Precautions for Storage

Store below 30°C in a dry place.

6.5. Nature and Contents of Container

Sachets of paper/aluminium foil/polythene laminate. One, seven, ten or thirty sachets in a cardboard outer. (Pack sizes printed in bold are currently sold).

6.6. Instructions for Use, Handling and Disposal

Fybogel Lemon granules are to be dispersed in water forming a drink.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited,
Dansom Lane,
HULL,
HU8 7DS,
England.

8. MARKETING AUTHORISATION NUMBER(S)

PL 00063/0024.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

24th April, 1995 / 20th August, 1997.

10 DATE OF REVISION OF THE TEXT

01/12/2020