SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Isogel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Isogel contains dried Ispaghula Husks 90% w/w

Excipient(s) with known effect

Sodium metabisulfite (E 223)
Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Small reddish granules

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Isogel is not absorbed from the G.I. tract, but it absorbs water to form a mucilaginous mass. This results in a purely mechanical stimulus to mass peristalsis without any purgative effect. It is for this reason that Isogel is not only an effective remedy for constipation, but is also of value in the treatment of diarrhoea, irritable bowel syndrome and the management of patients with a colostomy. Isogel is indicated in habitual constipation, including cases due to spastic colon, dietary insufficiencies and in patients with haemorrhoids or diabetes. It can be used to normalise the bowel movement in patients with mucous or ulcerative colitis.

Isogel is of help to patients with a colostomy as the formation of a well-formed, easily passed stool assists in the maintenance of cleanliness and the establishment of control.

4.2 Posology and method of administration

Route of administration: oral

The required quantity of Isogel should be stirred briskly into a glass of water and swallowed at once. Adequate fluid intake has to be maintained.

The product should be taken during the day at least ½ to 1 hour before or after intake of other medicines, not immediately prior to bed-time.

The effects start 12 -24 hours later.

Adults:	2 teaspoonfuls once or twice daily, preferably at mealtimes.
Children:	1 teaspoonful once or twice daily, preferably at mealtimes.
Elderly:	As for adults. Elderly or debilitated patients should be supervised whilst taking Isogel

Not recommended for use in children under 6 years of age (See section 4.4. 'Special warnings and precautions for use').

Not recommended for use in children below 12 years of age to whom an increased daily fibre intake may be advisable e.g. as an adjuvant in constipation predominant irritable bowel syndrome (See section 4.4. 'Special warnings and precautions for use').

The above dosage is only a general guide and it should be adjusted to suit the needs of each individual patient.

In diarrhoea the dose, usually 1 teaspoonful, is taken 3 times daily until symptoms abate.

If the symptoms persist during the use of the medicinal product for habitual constipation for more than 3 days, a doctor or a pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to the 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.

Isogel is contra-indicated in patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and cardia, potential or existing intestinal blockage (ileus), paralysis of the intestine or megacolon.

Patients who have difficulty in swallowing or any throat problems.

4.4 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 ispaghula husk 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.

If symptoms persist longer than 3 days, the patient should call a doctor or health care 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 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).

The use of ispaghula husk as an adjuvant to diet in hypercholesterolemia requires medical supervision.

This product contains sodium metabisulfite, which rarely may cause severe hypersensitivity reactions and bronchospasm.

This product contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Paediatric Population

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

Use is not recommended in children below 12 years of age to whom an increased daily fibre intake may be advisable e.g. as an adjuvant in constipation predominant irritable bowel syndrome. This is due to insufficient data on efficacy.

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 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
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

Isogel 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 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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card App in the Google Play or Apple App Store.

4.9 Overdose

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

Management
Attention should be paid to maintaining an adequate fluid intake, particularly if the granules have been taken without water, contrary to administration instructions and management should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Drugs for constipation; Bulk-forming laxatives; Ispaghula (Psylla seeds). **ATC Code:** A06AC01

Pharmacodynamic effects
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 a single administration. Sometimes the maximum effect is reached after 2 to 3 days.

In mild to moderate hypercholesterolemia a reduction of LDL cholesterol of approximately 7% has been reported. Investigations, which study the effect of ispaghula husk on the incidence of cardiovascular events and total mortality, are not available.

5.2 Pharmacokinetic properties

Absorption

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%.

Biotransformation
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 as 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 (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.

Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine solution (E127)
Sodium metabisulfite (E223)
Phosphoric acid
Gum mucilage
Purified water

Gum mucilage: Acacia tears, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed to protect from moisture.

6.5 Nature and contents of container

Cardboard outer cartons with greaseproof liners or polypropylene – polyethylene laminate sachets containing 150g, 165g, 200g and 300g. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Isogel is supplied as granules. The patient should stir the required quantity briskly into half a glass of water and swallow at once. Carbonated water may make swallowing easier.

7 MARKETING AUTHORISATION HOLDER

Soho Flordis UK Limited
1 Botanic Court,
Martland Park,
Wigan,
WN5 0JZ,
UK.
Trading as: Potters, Wigan WN5 0JZ

8 MARKETING AUTHORISATION NUMBER(S)

PL 44893/0032

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16/08/2012

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25/03/2021