Ispaghula

Egyiptomi útifűmag (ispaghula seed); Egyiptomi útifűmaghéj (ispaghula husk); Ispaghul, graine d' (ispaghula seed); Ispaghul (graine d'), tégument de la (ispaghula husk); Ispagula; Ispagula Kabuğu; Ispagulafrö (ispaghula seed); Ispagulafröskal (ispaghula husk); Ispagulansiemen (ispaghula seed); Ispagulansiemenkuori (ispaghula husk); Kepek; Kiaušininių gysločių sėklos (ispaghula seed); Kiaušininių gysločių sėklų luobelės (ispaghula husk); Łupina nasienna babki jajowatej (ispaghula husk); Nasienie babki jajowatej (ispaghula seed); Osemení jitrocele vejčitého (ispaghula husk); Plantaginis ovatae semen (ispaghula seed); Plantaginis ovatae seminis tegumentum (ispaghula husk); Psilio; Semeno jitrocele vejčitého (ispaghula seed); Zaragatona.

Шелуха Исфагулы (ispaghula husk)

Pharmacopoeias. Monographs for the husk and seed are included in *Eur.* (see p.vii) and *US*.

Ph. Eur. 6.2 (Ispaghula Husk; Plantaginis Ovatae Seminis Tegumentum). The episperm and collapsed adjacent layers removed from the seeds of *Plantago ovata* (*P. ispaghula*). The powdered drug loses not more than 12.0% of its weight on drying. Protect from light.

Ph. Eur. 6.2 (Ispaghula Seed; Plantaginis Ovatae Semen). The dried ripe seeds of *Plantago ovata* (*P. ispaghula*). The powdered drug loses not more than 10.0% of its weight on drying. Protect from light.

USP 31 (Psyllium Husk). The cleaned, dried seed coat (epidermis), in whole or in powdered form, separated by winnowing and threshing from the seeds of *Plantago ovata* (known in commerce as Blond Psyllium, Indian Psyllium, or Ispaghula), or from *Plantago arenaria* (*Plantago psyllium*), known in commerce as Spanish or French Psyllium.

USP 31 (Plantago Seed). The cleaned, dried, ripe seed of *Plantago ovata*, or of *Plantago psyllium*, or of *Plantago indica* (*P. arenaria*).

Psyllium Hemicellulose *(USAN)*

CAS — 9034-32-6.

Pharmacopoeias. In *US*.

USP 31 (Psyllium Hemicellulose). The alkali soluble fraction of the husk from *Plantago ovata* consisting of highly substituted arabinoxylan polysaccharides. These polysaccharides are linear chains of xylose units to which are attached single units of arabinose and additional xylose. Rhamnose, galactose, glucose, and rhamnosyluronic acid residues are also present as minor constituents. It contains not less than 75.0% of dietary soluble fibre, calculated on the dried basis. Store in airtight containers at a temperature of 25°, excursions permitted between 15° and 30°.

Psyllium Seed

Blešníkové semeno; Bolhafűmag; Flea Seed; Loppfrö; Nasienie płesznika; Psilio, semilla de; Psyllii semen; Psyllium, graine de; Psyliuminsiemen; Smiltyninių gysločių sėklos.

ATC — A06AC01.

ATC Vet — QA06AC01.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *US* under the title of Plantago Seed.

Ph. Eur. 6.2 (Psyllium Seed). The ripe, whole, dry seeds of *Plantago afra* (*P. psyllium*) or *Plantago indica* (*P. arenaria*). It loses not more than 14.0% of its weight on drying. Protect from light and moisture.

USP 31 (Plantago Seed). The cleaned, dried, ripe seed of *Plantago ovata*, or of *Plantago psyllium*, or of *Plantago indica* (*P. arenaria*) (see also Ispaghula, above).

Adverse Effects and Precautions

Large quantities of ispaghula and other bulk laxatives may temporarily increase flatulence and abdominal distension; hypersensitivity reactions have been reported. There is a risk of intestinal or oesophageal obstruction and faecal impaction, especially if such compounds are taken with insufficient fluid. Therefore, they should always be taken with at least 150 mL of water or other liquid. Ispaghula and bulk laxatives should not be taken immediately before going to bed because reduced gastric motility may impair intestinal passage and cause obstruction. They should be avoided by patients who have difficulty swallowing.

Bulk laxatives should not be given to patients with pre-existing faecal impaction, intestinal obstruction, or colonic atony.

Hypersensitivity. Hypersensitivity reactions associated with the ingestion or inhalation of ispaghula or psyllium have been reported.[1-9] Symptoms have included rash, rhinitis, urticaria, bronchospasm, and anaphylactic shock; in one case, anaphylaxis was fatal.[9] In most patients, sensitisation was thought to have occurred during occupational exposure.

1. Busse WW, Schoenwetter WF. Asthma from psyllium in laxative manufacture. *Ann Intern Med* 1975; **83:** 361–2.
2. Gross R. Acute bronchospasm associated with inhalation of psyllium hydrophilic mucilloid. *JAMA* 1979; **241:** 1573–4.
3. Suhonen R, *et al.* Anaphylactic shock due to ingestion of psyllium laxative. *Allergy* 1983; **38:** 363–5.
4. Zaloga GP, *et al.* Anaphylaxis following psyllium ingestion. *J Allergy Clin Immunol* 1984; **74:** 79–80.
5. Kaplan MJ. Anaphylactic reaction to "Heartwise". *N Engl J Med* 1990; **323:** 1072–3.
6. Lantner RR, *et al.* Anaphylaxis following ingestion of a psyllium-containing cereal. *JAMA* 1990; **264:** 2534–6.
7. Freeman GL. Psyllium hypersensitivity. *Ann Allergy* 1994; **73:** 490–2.
8. Vaswani SK, *et al.* Psyllium laxative-induced anaphylaxis, asthma, and rhinitis. *Allergy* 1996; **51:** 266–8.
9. Khalili B, *et al.* Psyllium-associated anaphylaxis and death: a case report and review of the literature. *Ann Allergy Asthma Immunol* 2003; **91:** 579–84.

Interactions

Ispaghula 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 B_{12}) and minerals (such as calcium, iron, or zinc). Intervals of 30 minutes to 1 hour are recommended between ispaghula and other drugs or food, although some recommend as much as 3 hours between bulk-forming laxatives and other drugs. The dose of insulin may need to be reduced in diabetic patients taking ispaghula.

Lithium. For reference to ispaghula possibly reducing the absorption of lithium, see Gastrointestinal Drugs, p.405.

Uses and Administration

Ispaghula seed, ispaghula husk, and psyllium seed are bulk laxatives (p.1693). They absorb water in the gastrointestinal tract to form a mucilaginous mass which increases the volume of faeces and hence promotes peristalsis. They are used in the treatment of constipation (p.1693), especially in diverticular disease (p.1695) and irritable bowel syndrome (p.1699), and when excessive straining at stool must be avoided, for example after anorectal surgery or in the management of haemorrhoids. The ability to absorb water and increase faecal mass means that they may also be used in the management of diarrhoea (p.1694) and for adjusting faecal consistency in patients with colostomies.

The usual oral dose is about 3.5 g one to three times daily, although higher doses have been given. It should be taken immediately after mixing in at least 150 mL water or fruit juice. The full effect may not be achieved for up to 3 days.

Ispaghula is also given for mild to moderate hypercholesterolaemia as an adjunct to a lipid-lowering diet. The recommended dose is about 7 g daily.

Hyperlipidaemias. Preparations of ispaghula have been reported[1-4] to lower serum-cholesterol concentrations in patients with mild to moderate hypercholesterolaemia. They have also been given with reduced doses of a bile-acid binding resin in the treatment of hyperlipidaemia,[5] which is reported to be effective and better tolerated than full doses of the resin alone. Similarly, psyllium supplementation with 10 mg of simvastatin was found to be as effective in lowering cholesterol as 20 mg of simvastatin alone.[6] However, ispaghula or psyllium should be regarded as adjuncts to dietary modification rather than substitutes for it. For a discussion of the hyperlipidaemias and their management, see p.1169.

1. Anderson JW, *et al.* Cholesterol-lowering effect of psyllium hydrophilic mucilloid for hypercholesterolemic men. *Arch Intern Med* 1988; **148:** 292–6.
2. Bell LP, *et al.* Cholesterol-lowering effects of psyllium hydrophilic mucilloid: adjunct therapy to a prudent diet for patients with mild to moderate hypercholesterolemia. *JAMA* 1989; **261:** 3419–23.
3. Anderson JW, *et al.* Cholesterol-lowering effects of psyllium intake adjunctive to diet therapy in men and women with hypercholesterolemia: meta-analysis of 8 controlled trials. *Am J Clin Nutr* 2000; **71:** 472–9.
4. Anderson JW, *et al.* Long-term cholesterol-lowering effects of psyllium as an adjunct to diet therapy in the treatment of hypercholesterolemia. *Am J Clin Nutr* 2000; **71:** 1433–8.
5. Spence JD, *et al.* Combination therapy with colestipol and psyllium mucilloid in patients with hyperlipidemia. *Ann Intern Med* 1995; **123:** 493–9.
6. Moreyra AE, *et al.* Effect of combining psyllium fiber with simvastatin in lowering cholesterol. *Arch Intern Med* 2005; **165:** 1161–6.

Preparations

BP 2008: Ispaghula Husk Effervescent Granules; Ispaghula Husk Granules; Ispaghula Husk Oral Powder;
USP 31: Psyllium Hydrophilic Mucilloid for Oral Suspension.

Proprietary Preparations (details are given in Part 3)
Arg.: Agarol Fibras Naturales†; Agiofibras; Herbaccion Laxante†; Konsyl; Lostamucil; Metamucil; Motional; Mucofalk; Plantaben; ***Austral.:*** Agiofibe; Ford Fibre; Fybogel; Metamucil; Mucilax†; Natural Fibre†; ***Austria:*** Agiocur; Laxans; Metamucil; ***Belg.:*** Colofiber; Fybogel†; Spagulax; ***Braz.:*** Agiofibra; Fibracare; Loraga†; Metamucil; Plantaben; ***Canad.:*** Laxucil; Metamucil; Mucillium; Natural Source Laxative†; Novo-Mucilax; Prodiem Plain†; ***Chile:*** Euromucil; Fibrasol; Metamucil†; Plantaben; ***Denm.:*** Vi-Siblin; ***Fin.:*** Agiocur; Laxamucil; Vi-Siblin; ***Fr.:*** Mucivital; Spagulax; Spagulax Mucilage; Transilane; ***Ger.:*** Agiocur; Flosa; Flosine; Laxiplant Soft†; Metamucil; Mucofalk; Pascomucil; ***Hong Kong:*** Agiocur; Fibermate; Fybogel†; Metamucil; Mucofalk; Naturlax; Transilane; ***India:*** Isogel; ***Indon.:*** Mucofalk; Mulax; ***Irl.:*** Fybogel; Regulan; ***Israel:*** Agiocur; Konsyl; Mucivital†; Planten†; ***Ital.:*** Agiofibre; Fibrolax; Planten; Psyllogel; ***Malaysia:*** Fybogel; Mucofalk; ***Mex.:*** Agiofibra; Fibromucil; Finalax; Fybogel; Hormolax; Konsyl†; Metamucil; Mucilag; Mugasin; Novagon; Plantaben; Siludane†; ***Neth.:*** Metamucil; Mucofalk; Regucol; Volcolon; ***Norw.:*** Lunelax; Vi-Siblin; ***NZ:*** Isogel; Metamucil; Mucilax; ***Philipp.:*** Fibermate; Mucofalk; ***Pol.:*** Mucofalk; ***Port.:*** Agiocur; Laxat; Mucofalk; Prontolax; Vetilax; ***S.Afr.:*** Agiobulk; Agiogel†; Fybogel; Metamucil†; ***Singapore:*** Fybogel; Mucilin; Mucofalk; ***Spain:*** Biolid; Cenat; Duphafibra; Laxabene; Laxisoft†; Metamucil; Plantaben; ***Swed.:*** Lunelax; Vi-Siblin; ***Switz.:*** Agiolax mite; Colosoft†; Laxiplant Soft; Metamucil; Mucilar; Valverde regulateur du transit intestinal granules†; ***Thai.:*** Agiocur†; Fybogel; Metamucil; Mucilin; Mucofalk†; ***Turk.:*** Otaci Musillium; ***UK:*** Fibrelief; Fybogel; Isogel; Ispagel; Konsyl†; Regulan; ***USA:*** Fiberall; Hydrocil Instant; Konsyl; Konsyl-D; Metamucil; Mylanta Natural Fiber†; Reguloid; Serutan; Syllact; ***Venez.:*** Agiofibe; Siliumbran.

Multi-ingredient: ***Arg.:*** Agiolax; Cholesterol Reducing Plan†; Gelax; Isalax Fibras; Kronolax†; Medilaxan; Mermelax; Prompt†; Rapilax Fibras; Salutaris; ***Austral.:*** Agiolax; Bioglan Psylli-Mucil Plus; Herbal Cleanse†; Nucolox; PC Regulax†; ***Austria:*** Agiolax; ***Belg.:*** Agiolax; Spagulax K; Spagulax Sorbitol; ***Braz.:*** Agiolax; Parapsyl; Plantax†; ***Canad.:*** Prodiem Plus†; ***Chile:*** Bilaxil; ***Cz.:*** Agiolax; ***Fin.:*** Agiolax; ***Fr.:*** Agiolax; Carres Parapsyllium; Filigel; Imegul†; Parapsyllium; Spagulax au Citrate de Potassium; Spagulax au Sorbitol; ***Ger.:*** Agiolax; ***Hong Kong:*** Agiolax; Fybogel Mebeverine†; ***Irl.:*** Fybogel Mebeverine; ***Israel:*** Agiolax; ***Ital.:*** Agiolax; Agioslim; Duolaxan†; Fibrolax Complex; Psyllogel Fermenti; ***Mex.:*** Agiolax; Psilumax; ***Neth.:*** Agiolax; ***Norw.:*** Agiolax; ***NZ:*** Nucolox†; ***Pol.:*** Agiolax; Laxamix; Otrebuski; ***Port.:*** Agiolax; Excess†; ***S.Afr.:*** Agiolax; ***Spain:*** Agiolax; ***Swed.:*** Agiolax; Vi-Siblin S; ***Switz.:*** Agiolax; Mucilar Avena; ***Thai.:*** Agiolax; ***Turk.:*** Otaci Diyet Life Psyllium Plus; ***UK:*** Cleansing Herbs; Fibre Dophilus; Fibre Plus; Fybogel Mebeverine; Lion Cleansing Herbs; Manevac; ***USA:*** Perdiem; Senna Prompt; ***Venez.:*** Agiolax; Avensyl; Fiberfull; Fibralax†; Senokot con Fibra†.

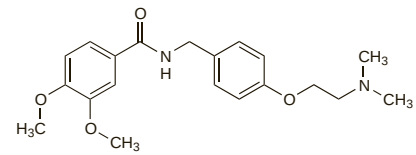
Itopride Hydrochloride *(rINNM)*

HC-803; Hidrocloruro de itoprida; HSR-803; Itopride, Chlorhydrate d'; Itopridi Hydrochloridum. *N*-{*p*-[2-(Dimethylamino)ethoxy]benzyl}veratramide hydrochloride.

Итоприда Гидрохлорид

$C_{20}H_{26}N_2O_4.HCl$ = 394.9.

CAS — 122898-67-3 (itopride).



(itopride)

Profile

Itopride hydrochloride is a substituted benzamide with general properties similar to those of metoclopramide (p.1747) that has been used for its prokinetic and antiemetic actions in oral doses of 50 mg three times daily before meals.

◊ References.

1. Holtmann G, *et al.* A placebo-controlled trial of itopride in functional dyspepsia. *N Engl J Med* 2006; **354:** 832–40.

Preparations

Proprietary Preparations (details are given in Part 3)
Cz.: Ganaton; ***India:*** Itoprid; ***Jpn:*** Ganaton; ***Malaysia:*** Ganaton.

Jalap

Jalap Root; Jalap Tuber; Jalapa; Jalapenwurzel; Vera Cruz Jalap.

Ялапа

Jalap Resin

Jalapa, resina de; Jalapenharz.

CAS — 9000-35-5.

Profile

Jalap is the dried tubercles of *Ipomoea purga* (=*Exogonium purga*) (Convolvulaceae). Jalap resin is a mixture of glycosidal resins obtained by extraction of jalap with alcohol and it has a drastic purgative and irritant action. It has been superseded by less toxic laxatives.