



12 July 2013
EMA/HMPC/313600/2013
Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Ispaghula husk

Plantago ovata Forssk., seminis tegumentum

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of ispaghula husk. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing ispaghula husk.

This summary is not intended to provide practical advice on how to use medicines containing ispaghula husk. For practical information about using ispaghula husk medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is Ispaghula husk?

Ispaghula husk is the common name for the seed coats of the plant *Plantago ovata* Forssk. The plant is cultivated or gathered to obtain the seeds for medicinal use.

Ispaghula husk is used without further processing or as preparations obtained by powdering the seed coats.

Herbal medicines containing ispaghula husk are usually available in solid forms to be taken by mouth.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that ispaghula husk can be used for the treatment of habitual constipation (constipation not caused by a physical change to an organ) and in conditions where softening of the stools is desirable to reduce pain when they are passed, such as anal fissures, haemorrhoids and after surgery to the anus or rectum. The HMPC also concluded that ispaghula husk can be used in people where an increase in the daily intake of dietary fibre may be advisable, such as patients with irritable bowel syndrome who are suffering from constipation or in combination with diet in patients with hypercholesterolaemia (high blood cholesterol levels).

Ispaghula husk should be taken with plenty of liquid. It should be taken during the day at least half an hour to one hour before or after taking other medicines and not immediately before bedtime. It can be



used in adults and children above the age of 6 years for the treatment of constipation and to soften the stools but should only be used in adults and children over the age of 12 years when used to increase the fibre intake. If constipation does not resolve after three days, a doctor or pharmacist should be consulted. The use of ispaghula husk in hypercholesterolaemia always requires medical supervision.

Detailed instruction on how to take ispaghula husk medicines and who can use them can be found in the package leaflet that comes with the medicine.

How does ispaghula husk work as a medicine?

Ispaghula husk contains dietary fibre, which when mixed with water forms a gel-like mass that works as a mild laxative (medicine used to treat constipation). It moves down the digestive system and makes the stools softer by increasing their water content. At the same time ispaghula husk lubricates the intestine which improves the transit of stools. By increasing the stool bulk it also increases the tension in the bowel wall which will trigger bowel movements.

The way ispaghula husk works in reducing blood cholesterol levels is not fully understood.

What evidence supports the use of ispaghula husk medicines?

The HMPC conclusions on the use of ispaghula husk medicines are based on their 'well-established use' in these conditions. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment of ispaghula husk to treat constipation, the HMPC considered a number of clinical studies involving over 900 patients that showed the effectiveness of ispaghula husk as a mild laxative. Studies that were carried out in patients with irritable bowel disease did not show an effect on the disease itself but showed benefits in those patients who were also suffering from constipation. Its effectiveness in softening stools has been shown in a number of studies comparing ispaghula husk with placebo (a dummy treatment) in patients with haemorrhoids. Several studies investigated the effects of ispaghula husk on blood cholesterol levels and found that treatment with ispaghula husk led to small reductions in blood cholesterol levels.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with Ispaghula husk medicines?

Side effects have been reported with ispaghula husk medicines, including flatulence and abdominal distension (swelling of the belly). There is a risk of a build-up of hard, dry stool, particularly if Ispaghula husk is swallowed without enough liquid. Allergic reactions including rhinitis (runny nose), conjunctivitis (reddening and inflammation of the white of the eye), bronchospasm (excessive and prolonged contraction of the airway muscles) and anaphylaxis (severe allergic reaction) may also occur. When handling the powder preparation, inhalation of the powder should be avoided as this may lead to allergic sensitization and the potential development of allergies.

The HMPC recommended that ispaghula husk should not be used in patients with a sudden change in bowel habit that persists for more than two weeks, and in patients with undiagnosed bleeding of the rectum and failure to pass stools following the use of a laxative. It should also not be used in patients with conditions that involve a narrowing of the stomach and gut, and patients who have difficulty swallowing or have problems with their throat.

Further information on the risks associated with ispaghula husk medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use.

How are ispaghula husk medicines approved in the EU?

Any applications for the licensing of medicines containing ispaghula husk have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of ispaghula husk medicines in EU Member States should be obtained from the relevant national authorities.

Other information about ispaghula husk medicines

Further information on the HMPC assessment of ispaghula husk medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use. For more information about treatment with ispaghula husk medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.