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Committee on Herbal Medicinal Products (HMPC)

## Herbal medicine: summary for the public

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### Ispaghula seed

*Plantago ovata* Forssk., semen

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

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

#### **What is ispaghula seed?**

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

Ispaghula seed is used in the form of whole, dried, seeds or as preparations obtained by powdering the seeds.

Herbal medicines containing ispaghula seed 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 seed 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.

Ispaghula seed 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 bed-time. It can be used in adults and children above the age of 6 years. If constipation does not resolve after three days a doctor or pharmacist should be consulted.



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

## **How does ispaghula seed work as a medicine?**

Ispaghula seed 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 seed 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.

## **What evidence supports the use of ispaghula seed medicines?**

The HMPC conclusions on the use of ispaghula seed 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 seed to treat constipation, the HMPC considered a number of clinical studies that were carried out with ispaghula husk which contains the same ingredients. Ispaghula husk has been studied in over 900 patients showing effectiveness as a mild laxative. The data on ispaghula husk support therefore the use of ispaghula seed as a laxative. The effectiveness of ispaghula seed in softening stools is based on its laxative effects and no specific data are available.

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

## **What are the risks associated with ispaghula seed medicines?**

Side effects have been reported with ispaghula seed 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 seed 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 seed 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 seed 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](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use).

## **How are ispaghula seed medicines approved in the EU?**

Any applications for the licensing of medicines containing ispaghula seed 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 seed medicines in EU Member States should be obtained from the relevant national authorities.

## **Other information about ispaghula seed medicines**

Further information on the HMPC assessment of ispaghula seed 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](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with ispaghula seed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.