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Committee on Herbal Medicinal Products (HMPC)

## Herbal medicine: summary for the public

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### Psyllium seed

*Plantago afra* L. et *Plantago indica* L., semen

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

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

#### **What is psyllium seed?**

Psyllium seed is the common name for the seed of the plant *Plantago afra* L. or *Plantago indica* L. The plant is cultivated or gathered to obtain the seeds for medicinal use.

Psyllium seed is used in the form of ripe, whole, dry seeds or as preparations made by powdering the seeds.

Herbal medicines containing psyllium 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 psyllium 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.

Psyllium 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 or children over the age of 6 years. If constipation does not resolve after 3 days,



advice from a doctor or pharmacist should be sought. Detailed instruction on how to take psyllium seed medicines and who can use them can be found in the package leaflet that comes with the medicine.

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

Psyllium seeds contain 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 psyllium 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 psyllium seed medicines?**

The HMPC conclusions on the use of psyllium seed medicines for treating habitual constipation and to soften stools are based on their 'well-established use'. 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, the HMPC considered a number of clinical studies with isphagula seed and isphagula husk which contains similar ingredients to psyllium seed, showing its effect as a mild laxative. The effectiveness of psyllium 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 psyllium seed medicines?**

Side effects have been reported with psyllium 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 psyllium 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 psyllium seed medicines should not be used in patients with a sudden change in bowel habit that continues for more than 2 weeks, and in patients with unexplained bleeding from the rectum and failure to pass stools after using 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 psyllium 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 psyllium seed medicines approved in the EU?**

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

## **Other information about psyllium seed medicines**

Further information on the HMPC assessment of psyllium 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 psyllium seed medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.