

25 September 2018 EMA/697392/2018

Senna pods

Senna alexandrina Mill. (Cassia senna L.; Cassia angustifolia Vahl), fructus

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

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

What are senna pods?

Senna pods is the common name for the fruit of the plant *Senna alexandrina* Mill. (*Cassia senna* L.; *Cassia angustifolia* Vahl).

The HMPC conclusions cover senna pod preparations that are obtained by drying and comminuting (reducing into tiny pieces) the fruit. The dried, comminuted fruits may also be put in a solvent (such as ethanol) to dissolve compounds and form an extract. All senna pod preparations are standardised to contain a defined amount of anthraquinones, which are substances linked with the activity of senna pods.

Herbal medicines containing senna pod preparations are usually available as herbal tea to be drunk, and in liquid or solid forms to be taken by mouth.

Senna pod preparations may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that senna pod preparations can be used short term for occasional constipation and for bowel cleansing before medical procedures needing bowel emptying (such as bowel radiology or colonoscopy).

Senna pod medicines should only be used in adults and adolescents over the age of 12 years. They should not be taken for longer than one week for occasional constipation, and if symptoms continue or get worse while taking the medicine, a doctor or pharmacist should be consulted. Usually it is sufficient



to take senna pod medicines two to three times a week. For bowel cleansing, senna pod medicines should be taken only once. Patients taking certain medicines should consult a doctor before taking senna pod preparations at the same time.

Detailed instructions on how to take senna pod medicines and who can use them can be found in the package leaflet that comes with the medicine.

How do senna pods work as a medicine?

Senna pod medicines contain anthraquinones. These stimulate bowel movements, encouraging the bowels to empty. They also alter the absorption of water and salt from the bowels. This increases the amount of water in the material in the gut and so softens it and allows it to pass along the gut more easily.

What evidence supports the use of senna pod medicines?

The HMPC conclusions on the use of these senna pod medicines for occasional constipation and bowel cleansing 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 laboratory studies, experts reports, extensive clinical experience as well as several studies in mostly elderly patients with long-term or severe constipation. These studies compared senna medicines, taken with fibres, with other treatments for constipation (such as lactulose). Overall, these studies showed that senna medicines taken with fibres were at least as effective as the comparator at treating constipation.

Several clinical studies were also assessed which showed that senna pods were effective at bowel cleansing.

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

What are the risks associated with senna pod medicines?

Side effects with senna pod medicines include allergic reactions, abdominal (belly) pain, spasm and diarrhoea. Long-term use may cause colouration of the lining of the intestine, which usually resolves when the patient stops taking the medicine, imbalance of water and salt in the body, presence of proteins and blood in the urine and yellow or red-brown colour of the urine. The frequency of these side effects is not known.

Senna pod medicines must not be taken by patients with blockages or stenosis (narrowing) of the intestines, intestinal atony (loss of strength or movement in bowel muscles), appendicitis, inflammatory bowel diseases (Crohn's disease, ulcerative colitis), unexplained abdominal pain or severe dehydration. They must also not be taken during pregnancy, when breastfeeding or by children under 12 years of age.

Long-term use of laxatives like senna pods should be avoided, as use for more than a short time may lead to the bowels not working properly and cause dependence on laxatives.

Further information on the risks associated with these senna pod medicines, including the appropriate precautions for their safe use, can be found in the monograph which is published on the Agency's website under the section 'Documents': ema.eu/medicine/herbal/sennae-fructus.

How are senna pod medicines approved in the EU?

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

Other information about senna pod medicines

Further information on the HMPC assessment of senna pod medicines, including details of the Committee's conclusions, can be found in the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/sennae-fructus. For more information about treatment with senna pod medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.