

Package leaflet: Information for the patient

Senna 7.5 mg 12 Years Plus

Senna Pods (Fruit)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1. What **Senna 7.5 mg Tablets 12 Years Plus** are and what they are used for
2. What you need to know before you take **Senna 7.5 mg Tablets 12 Years Plus**
3. How to take **Senna 7.5 mg Tablets 12 Years Plus**
4. Possible side effects
5. How to store **Senna 7.5 mg Tablets 12 Years Plus**
6. Contents of the pack and other information

1. What Senna 7.5 mg Tablets 12 Years Plus are and what they are used for

Senna 7.5mg Tablets 12 Years Plus contains Senna Pods (Fruit) which work as a stimulant laxative for the short-term relief of occasional constipation in adults and children over 12 years of age. Constipation is a fairly common and uncomfortable complaint. It usually involves difficult or irregular bowel movements, accompanied by hard, dry motions which can be painful to pass. Laxatives do not help with weight loss.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is "normal and regular" varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern. Constipation is an occasional problem for some people. For others, it may happen more often. It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Not drinking enough fluids
- Loss of 'tone' of the bowel muscles in older people
- Pregnancy
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally "off colour". Sometimes it causes headaches.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
 - Drink enough water so that you do not become dehydrated
 - Keep up your exercise and stay fit
 - Make time to empty your bowels when your body tells you
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Senna 7.5 mg Tablets 12 years Plus

Do not take Senna 7.5 mg Tablets 12 years Plus if you:

- Are allergic to Senna Pods (Fruit) or any of the other ingredients of this medicine (listed in section 6)
- Have a blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis)
- Have paralysis or lack of muscle tone in the bowel (atony)
- Have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- Have severe dehydration (water and electrolyte depletion).
- Have persistent or undiagnosed abdominal complaints e.g. pain, nausea or vomiting
- Have faecal impaction or rectal bleeding for which you don't know the cause, or blood in stools
- Have already taken a laxative and are still constipated
- Have had a sudden change in bowel habit that has lasted for more than 2 weeks
- Are pregnant or breastfeeding
- Have kidney or heart failure
- Are under 12 years of age, unless advised by a medical professional

Does this help with weight loss?

Stimulant laxatives (including Senna 7.5 mg Tablets 12 Years Plus) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives can cause the colon to stop reacting to usual doses of laxatives so that larger and larger amounts of laxatives may be needed to produce bowel movements.
- Laxative dependency occurs from overuse.

Warnings and Precautions:

Talk to your doctor or pharmacist before taking Senna 7.5 mg Tablets 12 Years Plus

- if you are taking medicines for a heart condition (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine), medicines inducing QT prolongation, diuretics, adrenocorticosteroids or liquorice root preparations.
- if you already need to take laxatives every day. The cause of the constipation should be investigated. Long term use of laxatives should be avoided.

If you are unsure about interactions with any medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought yourself, including herbal and homeopathic remedies.

When administering this product to incontinent adults, pads should be changed more frequently to prevent extended skin contact with faeces.

Children and adolescents:

Should not be used in children or adolescents under the age of 12 years.

Other medicines and Senna 7.5mg tablets 12 Years Plus:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products; with medicinal products which induce reversion to sinus rhythm (e.g. quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products inducing hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

Pregnancy, breast-feeding and fertility:

You should not use Senna Tablets if you are pregnant or breastfeeding because there is no evidence that it is safe to do so.

Senna 7.5mg Tablets 12 Years Plus contains lactose:

The product contains lactose. Each tablet contains 153 mg of lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

3. How to take Aspar Senna 7.5 mg Tablets 12 Years Plus

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

New users should start with the lowest dose and increase it to the maximum, if necessary. Once regularity has been regained dosage should be reduced and stopped.

The recommended dose is:

Adults, the elderly and children over 12 years: Take one to two tablets at night when required.

Use in children and adolescents

This medicine should not be used by children under 12 years of age.

Duration of use

Not to be used for more than 1 week. Usually it is sufficient to take this medicine up to two to three times a week.

Tell your doctor or pharmacist if:

- The symptoms worsen or persist during the use of the medicinal product
- There is no bowel movement within 3 days of use
- You need to take laxatives every day or if abdominal pain persists.

Do not take more than the leaflet tells you. Overuse can be harmful.

If you take more Senna 7.5mg Tablets 12 years plus than you should:

Consult your doctor and take this leaflet with you.

It may be harmful to take too much of this medicine or take it for too long. This is because it may lead to:

- A 'lazy bowel', where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation.
- Imbalance of fluids and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called 'hypokalaemia'). This can make you tired, dizzy, make your muscles weak and cause uneven heart-beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you forget to take Senna 7.5 mg Tablets 12 Years Plus

Do not take a double dose to make up for a forgotten dose.

If you stop taking Senna 7.5mg Tablets 12 Years Plus

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following or other side effects occur, stop taking this medicine and consult a doctor or pharmacist

- Abdominal pain, spasms and diarrhoea, in particular these effects may be experienced by patients with irritable colon. In these cases, a reduced dose may be necessary.
- Hypersensitivity (allergic) reactions, hives (skin bumps), skin itchiness or local or more widespread rash, or asthma.
- Chronic use may lead to albuminuria and haematuria which is albumin or red blood cells in the urine
- Yellow or red-brown discolouration of urine may occur, which is harmless
- Chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken
- Low potassium levels in the blood leading to muscle weakness and/or cramps
- Severe weight loss
- Changes in the shape of the finger and fingernail, muscular spasms and inflammation of bones and joints.

May make you more likely to catch infections. The frequency is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Senna 7.5 mg Tablets 12 Years Plus

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package.

Do not use after the expiry date which is stated on the carton after EXP.. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Senna 7.5mg Tablets 12 Years Plus contains

The active substance is powdered Alexandrian Senna Pods (Fruit) (*Senna alexandrina* Mill. (syn. *Cassia acutifolia* Delile and *Cassia angustifolia* Vahl)) equivalent to 7.5 mg of hydroxyanthracene glycosides, calculated as sennoside B

The other ingredients are: Lactose, sodium starch glycolate (Type A), Talc, colloidal anhydrous silica, magnesium stearate and bitter fennel.

What Senna 7.5mg Tablets 12 Years Plus looks like and contents of the pack

Senna 7.5 mg Tablets 12 Years Plus are uncoated round biconvex greenish-brown tablets available in blister packs of 24 or 60 tablets (not all pack sizes may be marketed)

Marketing Authorisation Holder and Manufacturer:

Aspar Pharmaceuticals Ltd
Albany House,
Acrewood way,
St Albans,
AL4 0JY, United Kingdom

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Senna 7.5 mg Tablets 12 Years Plus
Senna Pods Alexandrian Powder

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