

APPROVED

By Jasraj Manhas at 5:28 pm, Apr 11, 2023

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Typefaces: Helvetica Neue Roman, Bold and Black
Smallest Type: 8pt

Leaflet Size : 170 mm (W) x 270 mm (H)

Front

The diagram shows a leaflet front page with a total width of 170 mm and a total height of 270 mm. A vertical center fold is indicated at the top, with 5 mm margins on either side. The top edge has 10 mm margins on both sides. The left edge has a 5 mm margin at the top, followed by three 10 mm segments. A box at the top left is labeled 'SPACE FOR PHARMA CODE'. The main content area contains the following text and elements:

Legal status: P >12yrs
Package leaflet: Information for the user

Senease Twelve Years Plus 7.5 mg Tablets

Sennosides

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 has told you.

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

What is in this leaflet:

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

1. What Senease Twelve Years Plus 7.5 mg Tablets are and what it is used for

Senease Twelve Years Plus 7.5 mg Tablets contains Sennosides which work as a stimulant laxative for the short-term relief of occasional constipation. This medicine contains calcium sennosides. Sennosides are hydroxyanthracene glycosides derived from Senna Leaf. 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

2. What you need to know before you take Senease Twelve Years Plus 7.5 mg Tablets

Do not take Senease Twelve Years Plus 7.5 mg Tablets if you:

- are allergic to Calcium Sennosides or any of the other ingredients of this medicine (listed in section 6)
- have blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis)
- have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have paralysis or lack of muscle tone in the bowel (atony)
- 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 severe dehydration
- have already taken a laxative and you are still constipated
- have had a sudden change in bowel habit that has lasted for more than 2 weeks
- have kidney or heart failure
- are pregnant or breast-feeding
- are under 12 years of age

Does this help with weight loss?

Stimulant laxatives (including Senease Twelve Years Plus 7.5 mg Tablets) 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.
- Laxative dependency occurs from overuse and can cause the colon to stop reacting to usual doses of laxatives so that larger amounts of laxatives may be needed to produce bowel movements.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Senease Twelve Years Plus 7.5 mg Tablets if you:

- suffer from kidney disorders
- are taking medicines for a heart condition (e.g. cardiac glycosides, antiarrhythmic medicinal products e.g. quinidine) and medicinal products inducing QT-prolongation.
- are taking diuretics, adrenocorticosteroids or liquorice root preparations.

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

Leaflet Size : 170 mm (W) x 270 mm (H)

Back

Center Fold
5 mm 5 mm

10 mm 10 mm

5 mm 10 mm 10 mm

270 mm

170 mm

SPACE FOR PHARMA CODE

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

Taking other medicines and Senease Twelve Years Plus 7.5 mg Tablets
Tell your doctor or pharmacist before taking this medicine;
- If you have recently taken or might take any other medicines, including any obtained without a prescription.

Pregnancy and breast feeding
You should not use Senease Twelve Years Plus 7.5 mg Tablets if you are pregnant or breast feeding.

Senease Twelve Years Plus 7.5 mg Tablets contains Lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Senease Twelve Years Plus 7.5 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you or as described in this leaflet. 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 dose for each age group, if necessary, by one half of the initial dose each day. Once regularity has been regained dosage should be reduced and stopped.

For oral use only

For adults, the elderly and children over the age of 12 years:
The recommended dose is one to two tablets at night. The tablets should be taken with a glass of water.

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

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

Duration of use:
Normally it is sufficient to take this medicinal product up to two to three times a week. Not to be used for more than 1 week.

Consult your doctor, after taking this medicine:

- If symptoms worsen or persist
- If abdominal pain persists
- If there is no bowel movement within 3 days of use or laxatives are needed every day

If you take more tablets than you should:
Consult your doctor or pharmacist for advice, if you accidentally take too many Senease Twelve Years Plus 7.5 mg Tablets.

It may be harmful to

- Take too much of Senease Twelve Years Plus 7.5 mg Tablets or take Senease Twelve Years Plus 7.5 mg Tablets for too long

This is because it may lead to:

- Imbalance of fluid 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 an uneven heart-beat.
- 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.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you forget to take Senease Twelve Years Plus 7.5 mg Tablets:
If you miss a dose, take your next dose when it's due. Do not take two doses at the same time to make up for a missed dose. Always consult your doctor or pharmacist if you need further advice.

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 product and consult your doctor or pharmacist:

- allergic reactions such as local or more widespread, skin rash, hives (skin bumps) or itchiness around the anus.
- the product may produce abdominal pain, spasms and diarrhoea, in particular in patients with irritable colon.
- chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken
- 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 during the treatment, but is harmless

The frequency of the effects occurring is not known.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Senease Twelve Years Plus 7.5 mg Tablets

Keep this medicine out of the sight and reach of children. Store in the original container. Do not use Senease Twelve Years Plus 7.5 mg Tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of the 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 Senease Twelve Years Plus 7.5 mg Tablets contains
Each uncoated tablet contains Sennosides (as calcium salts) equivalent to 7.5mg hydroxyanthracene glycosides, calculated as Sennoside B.

The other ingredients are: Lactose monohydrate, Maize starch, Calcium hydrogen phosphate, and Magnesium stearate.

What Senease Twelve Years Plus 7.5 mg Tablets looks like and contents of the pack
Senease Twelve Years Plus 7.5 mg Tablets are light green to brown colour, round convex shaped uncoated tablet, plain on both sides.

Senease Twelve Years Plus 7.5 mg Tablets are available in blister packs of 60 and 100 tablets and in containers of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR
Manufacturer
Rx Farma Limited, Units 1-7, Colonial Way, Watford, Hertfordshire, WD24 4YR

If you would like this leaflet in different format or want to report any side effects please contact marketing authorisation holder listed above.

This leaflet was last revised in March 2023