

Package leaflet: Information for the user

SenEase 7.5 mg tablets

Sennosides

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What SenEase 7.5mg tablets are and what they are used for
2. What you need to know before you take SenEase 7.5mg tablets
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1. What SenEase 7.5mg tablet are and what they are used for

SenEase 7.5mg tablets are used for short term relief of occasional constipation.

SenEase 7.5mg tablets do not help with weight loss.

This medicine contains *calcium sennosides*. Sennosides are hydroxyanthracene glycosides derived from Senna Leaf.

2. What you need to know before you take SenEase 7.5mg tablets

Do not take SenEase 7.5mg tablets;

- If you are allergic to Calcium Sennosides or any of the other ingredients of this medicine (listed in section 6)

- If you have blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis)
- If you have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- If you have paralysis or lack of muscle tone in the bowel (atony)
- If you have persistent or undiagnosed abdominal complaints e.g. pain, nausea or vomiting
- If you have faecal impaction or rectal bleeding for which you don't know the cause, or blood in stools
- If you have severe dehydration
- If you have already taken a laxative and you are still constipated
- If you have had a sudden change in bowel habit that has lasted for more than 2 weeks
- If you have kidney or heart failure
- If you are pregnant or breast-feeding
- If you are under 12 years of age unless advised by a medical professional

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking SenEase 7.5mg tablets;

- If you suffer from kidney disorders
- If you have been told you have an intolerance to some sugars because this medicine also contains lactose monohydrate (15.82mg per tablet)

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

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

Taking other medicines and SenEase 7.5mg Tablets

Tell your doctor or pharmacist before taking this medicine;

- If you are taking medicines for a heart condition (e.g. cardiac glycosides, antiarrhythmic medicinal products e.g. quinidine) and medicinal products inducing QT-prolongation.
- If you are taking diuretics, adrenocorticosteroids or liquorice root preparations.
- 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 7.5mg tablets if you are pregnant or breast feeding.

3. How to take SenEase 7.5mg 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.

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.

Children over 6 years: Not recommended unless advised by a medical professional.

Children 6 years and under: Not recommended

Do not take more tablets than the label or leaflet tells you to:

New users should start with the lowest dose (one tablet) and increase it to the maximum dose (two tablets) if necessary. Once regularity has been regained, dosage should be reduced and treatment can then usually be stopped.

Duration of use:

Normally it is sufficient to take this medicinal product up to two to three times a week. Use for more than 1 – 2 weeks requires medical supervision.

Consult your doctor, after taking this medicine:

- If symptoms worsen or persist
- If abdominal pain persists
- If there is no bowel movement after 3 days and 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 tablets.

It may be harmful to

- Take too much of SenEase 7.5mg Tablets or take SenEase 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 7.5mg 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 7.5mg tablets

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

This medicinal product does not require any special storage condition.

Store in the original container.

Do not use SenEase 7.5mg 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 7.5mg tablet 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 7.5mg tablet looks like and contents of the pack

SenEase 7.5mg tablets are light green to brown color, round convex shaped uncoated tablet, plain on both sides.

SenEase 7.5mg tablets are available in blister packs of 20 and 60 tablets and in containers of 100 or 1000 tablets.

Pack sizes over 100 tablets should only be dispensed through pharmacies.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Special Concept Development (UK) Limited T/A Rx Farma
Units 1-7, 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 or email at medinfo@sigmaplc.co.uk

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