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Please note the above replaces our previous separate approval form.

Please sign and tick the appropriate box above.

Failing to do so could delay your job. Thank You in anticipation.



PATIENT INFORMATION LEAFLET
Legal status: **GSL >18yrs**

CARE SENNA 7.5mg TABLETS ADULT

SENNA PODS
(7.5mg Sennoside B)

**READ THIS LEAFLET CAREFULLY
BECAUSE IT CONTAINS IMPORTANT
INFORMATION FOR YOU**

This medicine is available without prescription. However, you still need to take Care Senna Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.
- If you experience any of the side effects listed in the leaflet, or if you notice any other side effects, please consult your doctor or pharmacist.

IN THIS LEAFLET:

1. What **Care Senna Tablets** are and what they are used for
2. Before you take **Care Senna Tablets**
3. How to take **Care Senna Tablets**
4. Possible side effects
5. How to store **Care Senna Tablets**
6. Further information

Consult your doctor, pharmacist or nurse:

- if your symptoms worsen or persist during the use of the medicinal product
- if there is no bowel movement after 3 days and laxatives are needed every day
- if abdominal pain persists.

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

If you take too many Care Senna Tablets: Consult your doctor and take this leaflet with you.

It may be harmful to:

- Take Care Senna Tablets for too long
 - Take too much of Care Senna Tablets
- This is because taking too much for too long 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 'hypo-kalaemia'). 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 Care Senna Tablets:

If you miss a dose, take your next dose at the usual time. 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.

4. POSSIBLE SIDE EFFECTS:

Like all medicines this product can cause side effects, but not everyone gets them.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist:

- The product may produce abdominal pain, spasms and diarrhoea, in particular in patients with irritable colon.
- Chronic use may lead to albuminuria and haematuria which is albumin or red blood cells in the urine.
- Chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken.
- Yellow or red-brown discolouration of urine may occur during the treatment, but is harmless.
- Allergic reactions such as local, or more widespread, skin rash, hives (skin bumps) or itchiness around the anus. The frequency is not known.
- If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or healthcare practitioner. 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 CARE SENNA TABLETS:

Keep out of the reach and sight of children.

Do not use Care Senna Tablets after the expiry date. The expiry date is printed on the blister and base of carton.

Store below 25°C, but do not freeze. Store in the original packaging.

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. FURTHER INFORMATION:

Each tablet contains:

Alexandrian Senna fruit (pods) (*Cassia senna* L.(*C. acutifolia* Delile) fruit) corresponding to 7.5 mg hydroxyanthracene glycosides, calculated as Sennoside B.

This product also contains:

Magnesium Stearate, Fennel Seed, Croscarmellose Sodium, Calcium Hydrogen Phosphate Dihydrate, Microcrystalline Cellulose, Colloidal Anhydrous Silica.

What Senna Tablets look like and contents of the pack

Senna Tablets are uncoated biconvex greenish tablets available in packs/blisters of 20.

Product Licence Holder and Manufacturer:

Soho Floridis UK Ltd., Wigan WN5 0JZPL 44893/0031

Distributed by: Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK.

If you would like a version of this leaflet in an alternative format, please call **01484 842217**

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1. WHAT CARE SENNA TABLETS ARE AND WHAT THEY ARE USED FOR:

Senna tablets contains Senna pods/Sennosides which work as a stimulant laxative for the short term relief of occasional constipation. 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. BEFORE YOU TAKE CARE SENNA TABLETS:

Do not take Care Senna Tablets:

- if you are allergic to Senna or any of the 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 paralysis or a lack of muscle tone in the bowel (atony)
- if you have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- if you have severe dehydration

Does this help with weight loss?

Stimulant laxatives (including Senna 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.
- 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

Consult your doctor, pharmacist or nurse before taking this medicine:

- if you suffer from kidney disorders
- 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 have faecal impaction or rectal bleeding for which you don't know the cause, or blood in stools and undiagnosed, acute or persistent gastro-intestinal complaints, e.g. abdominal pain, nausea and vomiting
- 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 18 years.

Taking other medicines:

You should also consult your doctor or pharmacist for advice if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding:

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

3. HOW TO TAKE CARE SENNA TABLETS:

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.

For oral use.

Adults and the elderly:

Take two tablets at bedtime when required. Swallow tablets whole with water.

This medicine should not be used by children under 18 years of age.

Duration of use

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

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