

#### PACKAGE LEAFLET: INFORMATION FOR THE USER Senokot Max Strength Tablets 12 Years Plus/Senna Pods

**Read this leaflet carefully because it contains important information for you.**

- 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.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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#### **1. What Senokot Max Strength Tablets 12 Years Plus is and what it is used for**

Senokot Max Strength Tablets 12 Years Plus contains Senna/Sennosides which work as a stimulant laxative for the short-term relief of occasional constipation. Senokot Max Strength Tablets 12 Years Plus contains calcium sennosides. 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 Senokot Max Strength Tablets 12 Years Plus**

**Do not take if you:**

- are allergic to any of the ingredients (for a full list of ingredients, see section 6)
- have blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis).
- have paralysis or a lack of muscle tone in the bowel (atony).
- have appendicitis, inflammatory bowel disease such as Crohn’s disease or ulcerative colitis.
- have severe dehydration.
- 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 your 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 breast-feeding.
- have kidney or heart failure.
- are under 12 years of age.

**Does this help with weight loss?**

Stimulant laxatives (Senokot Max Strength 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.

**Tell your doctor, pharmacist or nurse if:**

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

- you have been told you have an intolerance to some sugars because this medicine also contains lactose monohydrate (31.64 mg/tablet per tablet). When administering this product to incontinent adults, 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**

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

#### **3. How to take Senokot Max Strength Tablets 12 Years Plus**

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.

**Adults, the elderly and children 12 years and over:**

swallow one tablet at night.

**Do not exceed the stated dose**

**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 one week.

Tell a doctor, pharmasist or nurse if:

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

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

**If you take too many tablets:**

Consult your doctor take this leafet 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:

- ‘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 muscle 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 an uneven heart beat.
- dehydration making you thirsty, feel faint and giving you headaches. It can also mean that you cannot pass enough urine.

**If you miss a dose:**

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 the missed dose.

Always consult your doctor if you need further advice.

#### **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 reduction in dose may be necessary.
  - hypersensitivity (allergic) reactions, hives (skin bumps), skin itchiness or local or more widespread, rash or asthma.
  - can make you more likely to catch infections.
  - chronic use may lead to albuminuria and haematuria which is albumin or red blood cells in the urine.
  - yellow or red-brown discoloration 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
- The frequency is not known.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmasist 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.

#### **5. How to store**

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

Store below 30°C. Store in the original package.

Do not use after the expiry date shown on the pack (EXP month/year).

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 Senokot Max Strength Tablets 12 Years Plus contains**

Each tablet contains powdered Alexandrian Senna fruit (pods) (cassia senna L. (C. acutifolia Delille)) and Tinnevelly Senna fruit (pods) (Cassia angustifolia Vahl) equivalent to 15mg hydroxyanthracene glycosides, calculated as sennoside B.

Also contains: calcium phosphate, maize starch, magnesium stearate and lactose monohydrate.

**What your medicine looks like and the contents of the pack**

Senokot Max Strength Tablets 12 years Plus are available in pack sizes of 24 or 48 tablets.

Not all pack sizes may be marketed.

PL Holder and Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS

Manufacturer: RB NL Brands B.V. WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, Netherlands PL 00063/0770

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