5. HOW TO STORE SENNOSIDES 7.5 MG TABLETS

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister strip. 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 Sennosides 7.5mg tablets contains

Each tablet contains Sennosides (as calcium salts) equivalent to 7.5mg of Hydroxyanthracene glycosides, calculated as Sennoside B. Each tablet also contains 15mg of lactose monohydrate.

The other ingredients are

Microcrystalline Cellulose, Calcium Hydrogen Phosphate, anhydrous, Lactose Monohydrate, Maize Starch, Croscarmellose Sodium Povidone K30, Magnesium Stearate, Maltodextrin.

What Sennosides 7.5mg tablets looks like and contents of the pack

The tablets are Brown coloured, speckled, circular, uncoated tablets debossed 'BP' on one side and '1' on other side.

Aluminium PVC/PVDC blisters containing 20, 60 and 100 tablets. Not all Pack sizes may marketed.

Marketing Authorisation Holder and Manufacturer responsible for batch release

Marketing Authorisation Holder

Blue Bio Pharmaceuticals Limited, 5th Floor, Beaux Lane house, Mercer Street Lower, Dublin 2, Ireland

Manufacturer

Central Pharma (contract packing) Ltd, Caxton Road, Elm Farm Industrial Estate, Bedford MK 41 OXZ , United Kingdom

Distributed by

Alissa Healthcare Research Limited, Unit 5, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, United Kingdom, PO15 7FE

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To request a copy of this leaflet in Braille, large print or audio please call free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information: Product name: Sennosides 7.5 mg Tablets Reference Number: 33831/0029

PATIENT INFORMATION LEAFLET Sennosides 7.5 mg tablets

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 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 or pharmacist. 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

What is in this leaflet:

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

1. WHAT SENNOSIDES 7.5 MG TABLETS ARE AND WHAT THEY ARE USED FOR

Sennosides 7.5 mg tablets are used for the short term relief of occasional constipation. This medicine does not help with weight loss.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SENNOSIDES 7.5 MG TABLETS

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
- have kidney or heart failure

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 prolongation, diuretics, adrenocorticosteroids or liquorice root preparations
- you have been told you have an intolerance to some sugars because this medicine also contains lactose.

Additional information

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.

Other medicines and Sennosides 7.5mg tablets

Talk to your doctor or pharmacist if you are taking or have recently taken any of the medicines listed above or any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

This product is not recommended for use if you are pregnant or breast feeding.

3. HOW TO TAKE SENNOSIDES 7.5 MG TABLETS

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

For oral use only

The correct individual dose is the smallest required to produce a comfortable soft-formed motion.

Adults, the elderly and children over 12 years:

One to two tablets in a single dose at bedtime.

Children over 6 years:

One tablet at bedtime under medical guidance. The tablets should be taken with a glass of water.

Not recommended for use in children under 6 years and medical advice should be sought.

Do not take more tablets than recommended in the leaflet. New users should start with the lowest dose and increase it to the maximum dose if necessary. Once regularity has been regained, the dosage should be reduced and can usually be stopped.

Duration of use

Usually 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.

Tell a doctor, pharmacist or nurse 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

If the symptoms worsen or persist a doctor or a pharmacist should be consulted.

If you take more Sennosides 7.5 mg Tablets than you should

If you have accidentally taken too many Tablets, consult your doctor or pharmacist for advice.

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 longterm 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 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 forget to take Sennosides 7.5 mg Tablets

If you miss a dose, take your next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions about these tablets, 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 reduction in 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. The frequency of these effects occurring 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.