PATIENT INFORMATION LEAFLET FOR

SOFLAX TABLETS

SCHEDULING STATUS

S0

SOFLAX TABLETS (13,5 mg)

Sennosides A and B

Contains sugar: Lactose monohydrate 23,06 mg

Read all of this leaflet carefully because it contains important information for you

SOFLAX TABLETS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use SOFLAX TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SOFLAX TABLETS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What SOFLAX TABLETS is and what it is used for

SOFLAX TABLETS (Sennosides A and B) belongs to a class of medicine known as laxatives. SOFLAX TABLETS promotes bowel movement in the intestine.

SOFLAX TABLETS is indicated for the relief of occasional constipation.

2. What you need to know before you take SOFLAX TABLETS

Do not take SOFLAX TABLETS if you:

- are hypersensitive (allergic) to Sennosides A and B or any of the other ingredients of SOFLAX TABLETS (listed in **Section 6**)
- have blockage in your stomach with severe nausea, vomiting and an inability to pass wind or stools, fever, bloody stools, skin that appears yellow, severe tenderness when you touch your abdomen, swelling of the abdomen and bloating.
- are experiencing nausea (feeling sick) and vomiting
- are experiencing bloody stools
- suffer from heart failure
- have pressure on your spinal cord due to bloating
- have Crohn's disease (abdominal pain, diarrhoea, weight loss, fatigue, skin pallor, shortness of breath, light-headedness and dizziness or a fast heartbeat)
- use SOFLAX TABLETS concomitantly with other laxatives.

Warnings and Precautions

Take special care with SOFLAX TABLETS:

- if you develop dependency on laxatives and your bowel functions abnormally as the condition should be investigated

- when you have abdominal pain, nausea or vomiting unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus)
- if you notice blood in your stool or the use of laxatives does not promote bowel movement in the intestine as that indicates a serious condition. Discontinue use and consult a doctor.

Children and adolescents

SOFLAX TABLETS is not recommended for use in children under the age of 6 years.

Other medicines and SOFLAX TABLETS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

If you are currently taking any of the following medicines, please ask your doctor or pharmacist for advice before you start using SOFLAX TABLETS:

- Disopyramide, flecainide, mexiletine, propafenone and quinidine to slow down the heart rate.
- Diuretics (water pills) and liquorice root.

Pregnancy, breastfeeding and fertility

Do not use SOFLAX TABLETS if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent SOFLAX TABLETS may interfere with the daily

activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SOFLAX TABLETS affects them.

SOFLAX TABLETS contains lactose monohydrate

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take SOFLAX TABLETS.

3. How to take SOFLAX TABLETS

Do not share medicines prescribed for you with any other person.

Always take SOFLAX TABLETS exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The dosage should be the lowest required to produce a comfortable, soft-formed motion. This varies between individuals.

The recommended dosage for adults is one to two tablets once daily. It is suggested that the lowest dose is started with and increased daily until a comfortable motion is produced. If no bowel action has occurred after three days of increased dosage, the medication should be stopped and a doctor consulted.

Children over 6 years of age can be given half the adult dosage.

Your doctor will tell you how long your treatment with SOFLAX TABLETS will last.

If you have the impression that the effect of SOFLAX TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more SOFLAX TABLETS than you should

The major symptoms of overdose are griping pain and severe diarrhoea.

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

If you forget to take SOFLAX TABLETS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SOFLAX TABLETS can have side effects.

Not all side effects reported for SOFLAX TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOFLAX TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking SOFLAX TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SOFLAX TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- asthma (episodic wheeze, shortness of breath, difficult or laboured breathing, chest tightness and reduced activity with or without cough).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- abdominal pain such as cramps
- diarrhoea
- weight loss
- muscle loss
- lack of appetite
- fatigue
- decreased strength
- finger clubbing
- long facies
- muscle contractions
- joint stiffness
- swelling and tenderness of one or more joints
- any abnormal colouration of the urine

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online

under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of SOFLAX TABLETS.

5. How to store SOFLAX TABLETS

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original package.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What SOFLAX TABLETS contains

The active substance is Senna Extract equivalent to 13,5 mg of Sennosides A and B as calcium salts.

The other ingredients are lactose, magnesium stearate, maize starch, methyl paraben, microcrystalline cellulose, sodium carboxymethyl cellulose, sodium lauryl sulphate and talc.

Contains preservative: methylparaben 0,021 % *m/m.*

What SOFLAX TABLETS looks like and contents of the pack

SOFLAX TABLETS: Tan to dark brown flat circular tablet with bevelled edges. It has 'CIPLA' monogram embossed on one side and central break-line on the other.

SOFLAX TABLETS: The tablets are packed in Aluminium / PVC / PE / PVDC blister strips of 20 tablets in quantities of 20, 60, 100, 200 or 500 tablets per carton.

Holder of Certificate of Registration

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Botswana: S2 BOT1001643A

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