

SOFLAX

SCHEDULING STATUS

Not Scheduled

PROPRIETARY NAME (AND DOSAGE FORM)

SOFLAX (Tablets)

COMPOSITION

Each tablet contains Senna Extract equivalent to 13,5 mg of Sennosides A and B as calcium salts. Preservative content: Methylparaben 0,021% m/m

PHARMACOLOGICAL CLASSIFICATION :

A.11.5 Laxatives

PHARMACOLOGICAL ACTION :

Promotes bowel movement by one or more direct actions on the intestine.

Sennosides A and B are anthraquinone glycosides. These are hydrolysed by bacterial action in the colon to give free anthraquinones which promote bowel movement by increasing colonic peristalsis. Soflax acts within 6-12 hours.

INDICATIONS :

Soflax is indicated for the relief of occasional constipation.

CONTRA-INDICATIONS :

Soflax should not be used in patients who are hypersensitive to Sennosides A and B.

Senna should not be given to patients with intestinal obstruction or with undiagnosed abdominal symptoms, symptoms of or appendicitis, nausea and vomiting, rectal bleeding and congestive heart failure.

WARNING :

Prolonged or frequent use of Soflax may result in dependence on laxatives and loss of normal bowel function.

SOFLAX should not be used in the presence of abdominal pain, nausea or vomiting.

SOFLAX should not be used for a period longer than one week, unless directed by a doctor.

If you have noticed a sudden change in bowel habits that has persisted for a period longer than 2 weeks, consult a doctor before using SOFLAX.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

DOSAGE AND DIRECTIONS FOR USE :

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.

Not recommended for use in children under the age of 6 years.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS :

Senna may cause mild abdominal discomfort such as colic or cramps. Prolonged use can result in diarrhoea with excessive loss of water and electrolytes.

There is also the possibility with laxative abuse syndrome of developing an atonic (desensitized) non-functioning colon. Skin rashes have been reported.

Senna may cause discoloration of the urine and faeces.

Prolonged use of laxatives should be avoided. Care should be taken in patients with inflammatory bowel disease.

The use of Sennosides as a laxative may interfere with diagnostic tests results for the phenolsulphonphthalein test, as senna may colour the urine pink to red, red to violet or red to brown in the event of alkalinity and may also increase the rate of excretion of phenolsulphonphthalein.

Chronic use or overuse of laxatives may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract and this may interfere with potassium-retaining effects of potassium-sparing diuretics.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :

See side-effects and special precautions. Treatment is symptomatic and supportive.

IDENTIFICATION :

Tan to dark brown flat circular tablets with bevelled edges. It has 'CIPLA' monogram embossed on one side and a central breakline on the other side.

PRESENTATION :

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

STORAGE INSTRUCTIONS :

Store below 25°C in a dry place, away from children.

REGISTRATION NUMBER :

32/11.5/0607

NAME AND BUSINESS ADDRESS OF APPLICANT :

CIPLA LIFE SCIENCES (PTY) LTD.
Pasita Street, Rosen Heights,
Rosen Park,
BELLVILLE 7530

DATE OF PUBLICATION OF THIS PACKAGE

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