PROFESSIONAL INFORMATION FOR

SOFLAX TABLETS

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SOFLAX TABLETS (13,5 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Senna extract equivalent to 13,5 mg of Sennosides A and B as calcium salts.

Contains sugar: lactose monohydrate 23,06 mg per tablet.

Preservative content: methylparaben 0,021 % *m/m*.

For the full list of excipients, see **section 6.1.**

3. PHARMACEUTICAL FORM

Tablets.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SOFLAX TABLETS is indicated for the relief of occasional constipation.

4.2 Posology and method of administration

For oral administration.

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.

Paediatric population

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

4.3 Contraindications

SOFLAX TABLETS is contraindicated:

- in patients with hypersensitivity to Sennosides A and B or to any other excipients of SOFLAX TABLETS (see **section 6.1**).
- in patients with intestinal obstruction or undiagnosed abdominal symptoms, acute or persistent gastrointestinal complaints, and stenosis, atony, appendicitis, inflammatory bowel diseases (e.g., Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water or electrolyte depletion, nausea and vomiting, rectal bleeding and congestive heart failure.
- when used concomitantly with other laxatives.

4.4 Special warnings and precautions for use

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

SOFLAX TABLETS should not be used by patients suffering from faecal impaction and

undiagnosed, acute or persistent gastrointestinal complaints, e.g. abdominal pain, nausea or vomiting unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus).

SOFLAX TABLETS 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 TABLETS. 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.

If SOFLAX TABLETS is needed every day the cause of the constipation should be investigated.

Senna pods preparations, such as SOFLAX TABLETS, should only be used if a therapeutic effect cannot be achieved by a chance of diet or the administration of bulk forming medicines.

Prolonged and excessive use of SOFLAX TABLETS may lead to diarrhoea with excessive loss of water and electrolytes, particularly potassium leading to hypokalaemia. There is also the possibility of developing an atonic non-functioning colon.

Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria.

Care should be taken in patients with inflammatory bowel disease.

Patients with kidney disorders should be aware of possible electrolyte imbalance.

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.

4.5 Interaction with other medicines and other forms of interaction

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of digoxin and interacts with anti-dysrhythmic medicines with which include reversion to sinus rhythm (e.g., quinidine) and with medicines inducing QT prolongation.

Concomitant use with other medicines inducing hypokalaemia (e.g., diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no reports of undesirable or damaging effects during pregnancy and on the foetus when used at the recommended dosage schedule.

However, as a consequence of experimental data concerning a genotoxic risk of several anthranoids such as SOFLAX TABLETS, e.g., emodin and aloe-emodin, use is not recommended during pregnancy.

Breastfeeding

Use during breastfeeding is not recommended as there are insufficient data on the excretion of metabolites in breast milk.

Small amounts of active metabolites (rhein) are excreted in breast milk.

4.7 Effects on ability to drive and use machines

No known effects.

4.8 Undesirable effects

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ Class	Frequency	Side effects
Immune system disorders	*Frequency unknown*	Hypersensitivity, urticarial and hypogammaglobulinaemia.
Metabolism and nutrition disorders	*Frequency unknown*	Hypokalaemia and cachexia.
Respiratory, thoracic and mediastinal disorders	*Frequency unknown*	Asthma.
Gastrointestinal disorders	*Frequency unknown*	Abdominal pain such as cramps and colic, diarrhoea and gastrointestinal tract mucosal pigmentation.
Skin and subcutaneous tissue disorders	*Frequency unknown*	Pruritus and exanthema generalised.
Musculoskeletal and connective tissue disorders	*Frequency unknown*	Finger clubbing, tetany and hypertrophic osteoarthropathy.
Renal and urinary disorders	*Frequency unknown*	Chromaturia (discontinuation of urine may occur and may interfere with diagnostic tests)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Symptoms of overdose

The major symptoms of overdose are griping pain and severe diarrhoea with consequent losses of fluid and electrolytes.

Treatment of overdose

Treatment is symptomatic and supportive with generous amounts of fluid. Electrolytes, especially potassium, should be monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.11.5 Laxatives

ATC code: A06AB06

Sennosides A and B promote 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 TABLETS acts within 6 to 12 hours.

5.2 Pharmacokinetic properties

Absorption

The action of the sennosides is colon specific and does not depend upon systemic absorption.

The β-O-linked glycosides (sennosides) are neither absorbed in the upper gut nor split by human digestive enzymes. They are converted by the bacteria of the large intestine into the active metabolite (rhein anthrone). Aglyca are absorbed in the upper gut. Animal experiments

with radio-labeled rhein anthrone administered directly into the caecum demonstrated absorption < 10 %. In contact with oxygen, rhein anthrone is oxidised into rhein and sennidins, which can be found in the blood, mainly in the form of glucuronides and sulphates. After oral administration of sennosides, 3 to 6 % of the metabolites are excreted in urine; some are excreted in bile.

Most of the sennosides (ca. 90%) are excreted in faeces as polymers (polyquinones) together with 2 to 6 % of unchanged sennosides, sennidins, rhein anthrone and rhein. In human pharmacokinetic studies with senna pods powder (20 mg sennosides), administered orally for 7 days, a maximum concentration of 100 ng rhein/mL was found in the blood. An accumulation of rhein was not observed. Active metabolites, e.g. rhein, pass in small amounts into breast milk. Animal experiments demonstrated that placental passage of rhein is low.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

Magnesium stearate

Maize starch

Methyl paraben

Microcrystalline cellulose

Sodium carboxymethyl cellulose

Sodium lauryl sulphate

Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

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Mispel Street

Bellville

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Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

32/11.5/0607

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July 2000

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03 August 2023

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