# SENNA LAXATIVE- sennosides tablet P & L Development, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

## **Drug Facts**

## Active ingredient (in each tablet)

Sennosides 8.6 mg

## **Purpose**

Laxative

#### Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement within 6- 12 hours.

## **Warnings**

#### Do not use

laxative products for longer than 1 week unless directed by a doctor

## Ask a doctor before using if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that continues over a period of 2 weeks.

## Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after use of a laxative.
 These may indicate a serious condition.

## If pregnant or breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

take preferably at bedtime or as directed by a doctor

age	starting dosage	maximum dosage	
adults and children 12 years of age and	of age and 2 tablets once a day		
over	2 tablets office a day	day	
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day	
children 2 to under 6 years	1/2 tablets once a	1 tablet twice a day	
Children 2 to under 6 years	day		
children under 2 years	ask a doctor	ask a doctor	

### Other information

- each tablet contains: calcium 30 mg
- store at 25° C (77° F); excursions permitted between 15-30°C (59-86°F)

## **Inactive Ingredients**

croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil\*, silicon dioxide\*, sodium lauryl sulfate\*, stearic acid\*, talc\*, triacetin\*

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

Compare to the active ingredient in Senokot®†

regular strength

natural laxative

sennosides 8.6 mg

#### laxative

- natural vegetable laxative ingredient
- gentle, dependable
- overnight relief

#### tablets

†This product is not manufactured or distributed by Aviro Health L.P., distributor of Senokot®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

<sup>\*</sup>contains one or more of these ingredients

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

## **PL Developments**

200 Hicks Street

Westbury, NY 11590

## **Product Label**

## regular strength natural laxative

sennosides 8.6 mg





- · gentle, dependable
- overnight relief







## 100 tablets

эмдехь. Purpose



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

'This product is not manufactured or distributed by Aviro Health L.P., distributor of Senokot®.

#### CINESTIONS OF COMMONTS?? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

\*contains one or more of these ingredients

stearate, microcrystalline cellulose, mineral oil\*, silicon dioxide\*, sodium lauryl sulfate\*, stearic acid\*, falc\*, triacetin\* Inactive ingredients croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, magnesium

Drug Facts (continued)

#### ■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

esch tablet contains: calcium 30 mg

#### Other information

700		
children under 2 years	sak a doctor	зак а достог
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
adults and children 12 years of age and over	S tablets once a day	4 tablets twice a day
908	sparob gnithata	agesob mumixem

take breferably at bedtime or as directed by a doctor

#### Directions

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.

may indicate a serious condition.

Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative. These

- noticed a sudden change in bowel habits that continues over a period of 2 weeks
  - stomach pain nausea vomiting
    - Ask a doctor before use if you have
  - laxative products for longer than 1 week unless directed by a doctor Do not use

#### Warnings

- generally produces a bowel movement in 6 -12 hours
  - Lejienes occasional consphagon (illedniarity)

SASN

...gm 8.8 səbisonnə2

Active ingredient (in each tablet)

Drug Facts













#### **READYinCASE Regular Strength Laxative**

#### **SENNA LAXATIVE**

sennosides tablet

Product	Intorm	ation
riouuct		ıatıvı

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-731

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) SENNOSIDES 8.6 mg

### **Inactive Ingredients**

Ingredient Name	Strength
-----------------	----------

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

**DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP)

HYPROMELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

MINERAL OIL (UNII: T5L8T28FGP)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TRIACETIN (UNII: XHX3C3X673)

#### **Product Characteristics**

Color	brown	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	PS23

**Contains** 

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726- 731-10	1 in 1 BOX	03/26/2021	12/31/2025
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/26/2021	12/31/2025

## Labeler - P & L Development, LLC (800014821)

Revised: 4/2023 P & L Development, LLC