

SENNALAXATIVE- sennosides tablet
medsource pharmaceuticals

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 over	2 tablets once a day	4 tablets twice a 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 day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: **calcium 25 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, liquid paraffin*, magnesium stearate, maltodextrin*, microcrystalline cellulose, mineral oil*, polyethylene glycol*, polyvinyl alcohol*, silicon dioxide*, stearic acid*, sodium lauryl sulfate*, talc

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Senna Laxative

Standardized Senna Concentrate 8.6 mg

Natural Vegetable Laxative Ingredient

Gentle, overnight relief

†Compare to active ingredients in Senokot®

Tablets

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

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed By:

Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269

www.valuelabels.com

Product Label



SENNALAXATIVE

sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-965(NDC:50804-486)
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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	0813;AV;TCL080;S8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-965-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2019	
2	NDC:45865-965-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/31/2016	

Labeler - medsource pharmaceuticals (833685915)

Establishment

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	repack(45865-965)

Revised: 12/2019

medsource pharmaceuticals