SENOKOT-S- sennosides and docusate sodium tablet Purdue Products LP

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.

Senokot-S

(standardized senna concentrate and docusate sodium)

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 100000050 mg

Purpose

Stool softener

Laxative

Uses

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

Warnings

Do not use

- if you are now taking mineral oil, unless directed by a doctor
- laxative products for longer than 1 week unless directed by a doctor

Ask a doctor before use 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	2 tablets	4 tablets
years of age and over	once a day	twice a day
children 6 to under 12	1 tablet	2 tablets
years	once a day	twice a day
children 2 to under 6	1/2 tablet	1 tablet
years	once a day	twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: calcium 10 mg, sodium 4 mg VERY LOW SODIUM
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

Inactive ingredients dicalcium phosphate,D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium benzoate, talc, and titanium dioxide

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Manufactured for:

Purdue Products L.P. Stamford, CT 06901-3431

By:

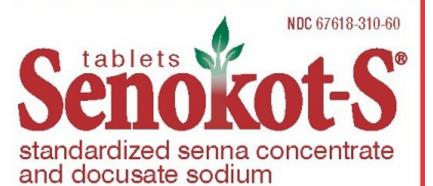
Purdue Pharma 575 Granite Court Pickering, ON L1W 3W8, Canada

302887-0A

Senokot-S 60 Tablets Carton

NDC: 67618-310-60

Works Gently. Works Overnight.™







Natural Vegetable Laxative Ingredient <u>plus</u> Stool Softener

60 tablets
Works in 6-12 hrs

SENOKOT-S

standardized senna concentrate and docusate sodium tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:67618-310
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNOSIDES (SENNOSIDES)	SENNOSIDES	8.6 mg	
DO CUSATE SO DIUM (DO CUSATE)	DOCUSATE SODIUM	50 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US			
D&C YELLOW NO. 10			
FD&C YELLOW NO. 6			
EGG PHO SPHO LIPIDS			
MAGNESIUM STEARATE			
CELLULO SE, MICRO CRYSTALLINE			
POLYETHYLENE GLYCOLS			
POLYVINYL ALCOHOL			
STARCH, CORN			
SO DIUM BENZO ATE			
TALC			
TITANIUM DIO XIDE			

Product Characteristics			
Color	ORANGE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	P
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	:67618-310-04	4 in 1 BLISTER PACK		
2 NDC	:67618-310-01	1 in 1 CARTON		
2		10 in 1 BLISTER PACK		
3 NDC	:67618-310-30	1 in 1 CARTON		
3		30 in 1 BOTTLE, PLASTIC		
4 NDC	:67618-310-60	1 in 1 CARTON		
4		60 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/1974	

Labeler - Purdue Products LP (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment			
Name	Address	ID/FEI	Business Operations
Purdue Pharma		250955291	MANUFACTURE(67618-310)

Revised: 9/2013 Purdue Products LP