SENNA-S- senna-s tablet Pioneer Life Sciences, 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.

Active Ingredients (in each tablet)

Docusate Sodium 50 mg Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses:

- Relieves occasional constipation (irregularity).
- Generally produces a bowel movement in 6 to 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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

DIRECTIONS

Take preferably at bedtime or as directed by a doctor.

age	starting dosage	maximum dosage
adults & 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 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

OTHER INFORMATION

- Each tablet contains: Calcium 19.92 mg, Sodium 5.61 mg VERY LOW SODIUM
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

Croscarmellose Sodium, Colloidal Silicon Dioxide, Dicalcium Phosphate, F D & C Red, Hypromellose, Magnesium Stearate,

Microcrystalline Cellulose, Maltodextrin, Polyethylene Glycol, Stearic acid Powder, Titanium Dioxide.

QUESTIONS OR COMMENTS?

Call toll-free 1 (732) 689-5070 Monday through Friday 9 am to 5 pm EST.

PRINCIPAL DISPLAY PANEL



Orug Facts (continued

Noticed a sudden change in bowel habits that continues over a period of 2 weeks.

Stop use and ask a doctor if you have:

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 Rectal bleeding or fail to have a bowel movement after use of a laxative. These KEEP OUT OF REACH OF CHILDREN In case of overdose, get medical help or

contact a Poison Control Center (1-800-222-1222) right away.

Directions

starting dosage maximum dosage Take preferably at bedtime or as directed by a doctor. 4 tablets twice a day ask a doctor twice a day twice a day 2 tablets 2 tablets once a day 1/2 tablet once a day ask a doctor once a day 1 tablet adults & children 12 years of children 2 to under 6 years under 12 years children under age and over children 6 to 2 years

Other information:

■ Each tablet contains: Calcium 19.92 mg, Sodium 5.61 mg VERY LOW SODIUM permitted between 15°C-30°C (59°-86°F) ■ Store at 25°C (77°F); excursions

nactive Ingredients

Dioxide, Dicalcium Phosphate, FD & C Red Croscarmellose Sodium, Colloidal Silicon Polyethylene Glycol, Stearic acid Powder, Microcrystalline Cellulose, Maltodextrin, Hypromellose, Magnesium Stearate, Itanium Dioxide

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Glue Area

SENNA-S

senna-s tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-030
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients	
Ingredient Name	Strength
Croscarmellose Sodium (UNII: M280L1HH48)	

Silicon Dioxide (UNII: ETJ7Z 6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Maltodextrin (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	none
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:72090-03	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/29/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 10/2023 Pioneer Life Sciences, LLC