SENNA-S- docusate sodium 50 mg sennosides 8.6 mg tablet, film coated Bryant Ranch Prepack

® Tablets

SPL UNCLASSIFIED SECTION

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 INGREDIENT (IN EACH TABLET)

Docusate Sodium 50 mg Sennosides 8.6 mg

PURPOSE

Stool softener

Stimulant laxative

USES

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

WARNINGS

Do not use

- this product if you are presently 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
- do not exceed maximum dosage

age	starting dosage	maximum dosage
adults and children 12 years of age or older	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 4 mg, sodium 8 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, stearic acid, titanium dioxide

HOW SUPPLIED

Docusate Sodium 50 mg & Sennosides 8.6 mg

NDC 63629-8908-1: 1000 Tablets in a BOTTLE

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504

Docusate Sodium 50 mg & Sennosides 8.6 mg Stool Softner/Laxative stool softner plus natural vegetable laxative



Each tablet contains: Docusate Sodium 50 mg; Sennosides 8.6 mg; Calcium 4 mg; Sodium 8 mg.

Tamper Evident: Do not use if printed

Directions: Take preferably at bedtime or as directed by a doctor, do not exceed maximum dosage.

Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

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

NDC 63629-8908-1

Senna-S Stool Softener/Laxative safety seal under cap is broken or missing. stool softener plus natural vegetable laxative

50 mg/8.6 mg



1000 Tablets

Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA

Manufactured by: AACE Pharmaceuticals, Inc.



SENNA-S

docusate sodium 50 mg sennosides 8.6 mg tablet, film coated

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:63629-8908(NDC:71406-106) **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)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	S6

Contains

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:63629- 8908-1	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	08/30/2019	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-8908), RELABEL(63629-8908)

Revised: 4/2024 Bryant Ranch Prepack