

SENNOSIDES AND DOCUSATE SODIUM- sennosides and docusate sodium tablet

American Health Packaging

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.

Sennosides and Docusate Sodium Tablets Natural Vegetable Laxative with Stool Softener 0462201/0621

Active ingredient (in each tablet)

Docusate Sodium	50 mg
Sennosides	8.6 mg

Purpose

Stool softener
Laxative

Uses

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

Warnings

Do not use for more than one week unless directed by a doctor.

Ask a doctor before use if you

- have abdominal pain, nausea or vomiting
- are taking mineral oil
- have noticed a sudden change in bowel habits that lasts over two 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

- do not exceed 8 tablets in 24 hours
- Adults and children 12 years of age and older take 2 tablets once a day preferably at bedtime; increase as needed, or as directed by a doctor; the maximum dose should be 4 tablets in the morning and 4 tablets at bedtime
- Children under 12 years ask a doctor

Other information

- each tablet contains: **calcium 20 mg, sodium 3 mg**
- store at controlled room temperature
- **Keep this and all drugs out of reach of children.**
- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, FD&C yellow #6 lake, hypromellose, magnesium stearate, PEG, silica, talc, titanium dioxide.

PACKAGING INFORMATION

The drug product contained in this package is from NDC # 57896-555, Geri-Care Pharmaceuticals Corp.

Distributed by:

American Health Packaging, Columbus, Ohio 43217

762201

0462201/0621A

Package/Label Display Panel - Carton - 8.6 mg/50 mg

NDC 60687-**622**-01

Sennosides* and Docusate Sodium Tablets
Natural Vegetable Laxative with Stool Softener
*Standardized Senna Concentrate

8.6 mg/50 mg

100 Tablets (10 x 10)



(01) 0 03 60687 622 01 9

Drug Facts

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Sennosides 8.6 mg.....	Laxative

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Drug Facts (continued)

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Sennosides and Docusate
Sodium Tablet
Laxative/Stool Softener
8.6 mg/50 mg

SENNOSIDES AND DOCUSATE SODIUM
sennosides and docusate sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-622(NDC:57896-555)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	PSD22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-622-01	100 in 1 BOX, UNIT-DOSE	08/03/2021	
1	NDC:60687-622-11	1 in 1 BLISTER PACK; 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	08/03/2021	

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(60687-622)

Revised: 8/2022

American Health Packaging