

LAXATIVE DOCUSATE SODIUM WITH SENNA- docusate sodium and sennosides tablet, coated
TOPCO ASSOCIATES 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.

Laxative Docusate Sodium with Senna

Drug Facts

Active ingredients (in each tablet)	Purposes
Docusate sodium 50 mg	Stool softener
Sennosides 8.6 mg	Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.

adults and children 12 years and | take 2-4 tablets daily

over	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2 years	ask a doctor

Other information

- **each tablet contains:** calcium 20 mg, sodium 3 mg (low sodium)
- store between 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide

Questions?

Call **1-888-423-0139**

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

NDC 36800-154-01

*Compare to the active ingredients
in Colace® 2-IN-1

Stool
Softener
+ Stimulant
Laxative

DOCUSATE SODIUM 50 mg
STOOL SOFTENER

SENNOSIDES 8.6 mg
STIMULANT LAXATIVE

For Relief of
Occasional Constipation

- Effective
- Reliable
- Comfortable

100 TABLETS

actual size



LAXATIVE DOCUSATE SODIUM WITH SENNA

docusate sodium and sennosides tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-861
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
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Anhydrous Dibasic Calcium Phosphate (UNII: L11K75P92J)	
FD&C Blue No. 2--Aluminum Lake (UNII: 4AQJ3LG584)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
Aluminum Oxide (UNII: LMI26O6933)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
Talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	S154
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-861-01	1 in 1 CARTON	05/01/2021	
1		100 in 1 BOTTLE; 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	05/01/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)