

**DOCUSATE SODIUM AND SENNOSIDES- docusate sodium and sennosides capsule, gelatin coated
SOFTGEL HEALTHCARE PRIVATE LIMITED**

Docusate Sodium 50 mg & Sennosides 8.6 mg Capsules(Orange)

Active ingredient (in each softgel)

Docusate Sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses

- relieves occasional constipation (irregularity)
- generally causes 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 movements 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 be signs of 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

adults and children 12 years of age and older

children 6 to 12 years

children under 6 years of age

Starting Dosage

2 softgels once a day

1 softgel once a day

ask a doctor

Maximum Dosage

4 softgels twice a day

2 softgels twice a day

ask a doctor

Other information

- **each softgel contains:** Sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°- 30°C (59°- 86°F)

Inactive ingredients

colloidal silicon dioxide, FD&C yellow no.6, gelatin, glycerin, polyethylene glycol 400, povidone K 30, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide, yellow wax

NDC 35916-0453-1 Compare to Senokot-S® active ingredients¹

Docusate Sodium 50 mg & Sennosides 8.6 mg Capsules

Softgels
Dual Action

- Gently relieves constipation
- Stool softener



500 SOFTGELS

Drug Facts	
Purpose	Stool softener Laxative
Active ingredient (in each softgel)	Docusate Sodium 50 mgStool softener Sennosides 8.6 mgLaxative
Uses	relieves occasional constipation (irregularity) generally causes 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 movements 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 be signs of a serious condition.
If pregnant or breast-feeding	ask a health professional before use.
Keep out of reach of children.	In case of accidental overdose, seek professional assistance or contact a Poison Control Center right away.
Directions	take preferably at bedtime or as directed by a doctor.
Age	Starting Dosage Maximum Dosage
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children under 6 years of age	ask a doctor ask a doctor
Other information	each softgel contains: Sodium 3 mg store at 25°C (77°F); excursions permitted between 15°- 30°C (59°- 86°F)
Inactive ingredients	Propylene glycol, Povidone, Colloidal Silicon Dioxide, Yellow wax, Polyethylene glycol 400, Gelatin, Glycerin, Sorbitol Sorbitan Solution, FD&C Yellow No.6, Titanium dioxide and Purified water.

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Manufactured by:
Softgel Healthcare Pvt. Ltd.,
Survey No. 2071,
Vandalur-Kelambakkam Road,
Pudupakkam Village,
Kanchipuram District,
Tamilnadu - 603 103, India.
Mfg. Lic. No.: XXXXXXXXXXXXX



Unvarnished Area
LH - 25x16 mm

NDC 35916-0453-1 Compare to Senokot-S® active ingredients¹

Docusate Sodium 50 mg & Sennosides 8.6 mg Capsules

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<u>DOCUSATE SODIUM 50 MG AND SENNOSIDES 8.6 MG SOFTGELATIN CAPSULE</u>		Imprint
Each Soft Gelatin Capsule Contains: (Docusate Sodium USP 50 mg and Sennosides USP 8.6 mg)		
BATCH NO :	NDC NO :	35916-0453-3
MFG DATE :	GROSS WT :	
EXP DATE :	NET WT :	
QUANTITY :	SHIPPER NO. :	
WARNING: KEEP OUT OF REACH OF CHILDREN		
STORAGE STORE AT 25°C (77°F); EXCURSIONS PERMITTED BETWEEN 15°- 30°C (59°- 86°F)		
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS.		
MANUFACTURED BY: SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND) LABELLER CODE: 35916 LIC NO:XXXX		MANUFACTURED FOR
CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"		

DOCUSATE SODIUM AND SENNOSIDES

docusate sodium and sennosides capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0453
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
WATER (UNII: 059QF0KO0R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (opaque)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	902
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0453-1	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2024	
2	NDC:35916-0453-3	2 in 1 BOX	06/12/2025	
2		3000 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	06/04/2024	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED