DOCUSATE SODIUM AND SENNOSIDES- docusate sodium and sennosides capsule, gelatin coated Softgel Healthcare Pvt Ltd

Docusate Sodium 50 mg & Sennosides 8.6 mg Capsules

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 accidental overdose, seek professional assistance or contact a Poison Control Center right away.

Directions

take preferably at bedtime or as directed by a doctor.

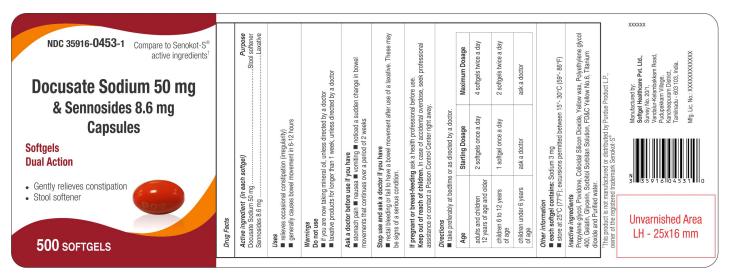
| Age | Starting Dosage | Maximum Dosage |
|---|-------------------------|----------------------|
| adults and children 12 years of age and | 2 softgels once a | 4 softgels twice a |
| older | day | day |
| children 6 to 12 years | 1 softgel once a day | , 2 softgels twice a |
| children o to 12 years | 1 30 reger office a day | day |
| 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.



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 |
| NDC:35916- 0453-1 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 06/04/2024 | |

| 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 Pvt Ltd (675584180)