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

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

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.

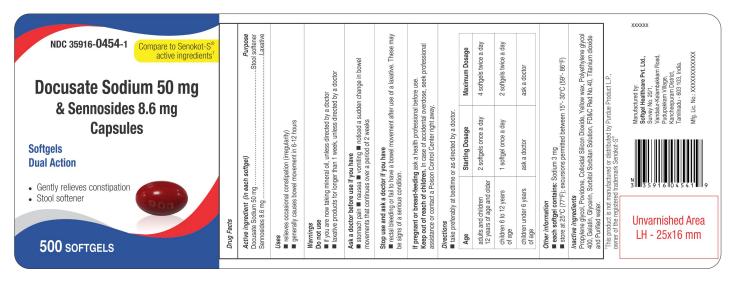
| Age | Starting Dosage | Maximum Dosage |
|---|-----------------------|------------------------|
| adults and children 12 years of age and older | 2 softgels once a day | 4 softgels twice a day |
| children 6 to 12 years of age | 1 softgel once a day | 2 softgels twice a day |
| children under 6 years 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 Red No.40, 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:35916-0454 | |
| 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 | |
| POVIDONE K30 (UNII: U725QWY32X) | | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |
| WATER (UNII: 059QF0KO0R) | | |
| GELATIN (UNII: 2G86QN327L) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | |

| Product Characteristics | | | | |
|-------------------------|--------------|--------------|----------|--|
| Color | red (opaque) | Score | no score | |
| Shape | OVAL | Size | 12mm | |
| Flavor | | Imprint Code | 903 | |
| Contains | | | | |

| ı | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| : | NDC:35916- 0454-1 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 06/22/2024 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M007 | 06/22/2024 | |
| OTC Monograph Drug | M007 | 06/22/2024 | |

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 6/2024 Softgel Healthcare Pvt Ltd