# LEADER SENNA PLUS STOOL SOFTENER LAXATIVE SOFTGEL- docusate sodium, sennosides capsule, liquid filled Cardinal Health 110, LLC. DBA Leader

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# **LEADER**<sub>TM</sub> Senna Plus Stool Softener Laxative SOFTGELS

### **Drug Facts**

# Active ingredients (in each softgel)

Docusate sodium 50 mg Sennosides 8.6 mg

### **Purpose**

Stool softener Laxative

#### Uses

- relieves occasional constipation (irregularity)
- generally produces a 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 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 preferably at bedtime or as directed by a doctor

| Age  | Starting<br>Dosage    | Maximum<br>Dosage         |
|--|-----------------------|---------------------------|
| adults and children 12 years of age and over | 2 softgels once a day | 4 softgels<br>twice a day |

| c | hildren 6 to under 12 years  | 1 softgel once<br>a day | 2 softgels<br>twice a day |
|---|------------------------------|-------------------------|---------------------------|
| C | hildren under 6 years of age | ask a doctor            | ask a doctor              |

#### Other information

- each softgel contains: calcium 4 mg, sodium 4 mg
- store at room temperature between 20°-25°C (68°-77°F)

### Inactive ingredients

colloidal silicon dioxide, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide, yellow bees wax

#### Questions or comments?

Call 1-800-200-6313

# COMPARE TO SENOKOT-S® active ingredients\*

#### **Dual Action**

Standardized Senna Concentrate

All LEADER™ Brand Products Have A **100% Money Back Guarantee** Return to place of purchase if not satisfied.

#### **Cardinal**Health™

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313 Essential to Care™ Since 1979

Product of India

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

# READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

# Overnight, gentle laxative

\*This product is not manufactured or distributed by Atlantis Consumer Healthcare Inc., owner of the registered trademark Senokot-S $^{\otimes}$ 

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#### **Packaging**





#### **DRUG FACTS LABEL**

| Drug Facts Active ingredients (in each soft Docusate sodium 50 mg   | · · · · · · · · · · · · · · · · · · ·                         | PurposeStool softenerLaxative                                    |  |
|---|---|--|--|
| <ul> <li>Uses</li> <li>■ relieves occasional constipation (irregularity)</li> <li>■ generally produces a bowel movement in 6-12 hours</li> </ul>  |   |  |  |
| 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 preferably at bedtime or as directed by a doctor  Age Starting Dosage Maximum Dosage  |   |  |  |
| adults and children 12 years of age and over<br>children 6 to under 12 years<br>children under 6 years of age   | 2 softgels once a day<br>1 softgel once a day<br>ask a doctor | 4 softgels twice a day<br>2 softgels twice a day<br>ask a doctor |  |

# Drug Facts (continued)

## Other information

- each softgel contains: calcium 4mg, sodium 4mg
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docusate sodium, sennosides capsule, liquid filled

#### **Product Information Product Type Item Code (Source)** HUMAN OTC DRUG NDC:70000-0685 **Route of Administration** ORAL

| Active Ingredient/Active Moiety |                 |  |  |  |
|---------------------------------|-----------------|--|--|--|
| <b>Basis of Strength</b>        | Strength        |  |  |  |
| DOCUSATE SODIUM                 | 50 mg           |  |  |  |
| SENNOSIDES                      | 8.6 mg          |  |  |  |
|                                 | DOCUSATE SODIUM |  |  |  |

| Inactive Ingredients                       |          |  |  |  |
|--|----------|--|--|--|
| Ingredient Name                            | Strength |  |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)         |          |  |  |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       |          |  |  |  |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L)    |          |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                |          |  |  |  |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) |          |  |  |  |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)   |          |  |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |          |  |  |  |
| WATER (UNII: 059QF0KO0R)                   |          |  |  |  |
| SORBITOL (UNII: 506T60A25R)                |          |  |  |  |
| SORBITAN (UNII: 6O92ICV9RU)                |          |  |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)        |          |  |  |  |
| YELLOW WAX (UNII: 2ZA36H0S2V)              |          |  |  |  |

| Product Characteristics |        |              |          |  |
|-------------------------|--------|--------------|----------|--|
| Color                   | orange | Score        | no score |  |
| Shape                   | OVAL   | Size         | 12mm     |  |
| Flavor                  |        | Imprint Code | 902      |  |
| Contains                |        |              |          |  |

| P | Packaging            |   |                         |                       |  |  |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| 1 | NDC:70000-<br>0685-1 | 1 in 1 CARTON                                     | 07/16/2024              |                       |  |  |
| 1 |                      | 60 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M007  | 07/16/2024              |                       |  |
|                       |   |                         |                       |  |

# Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Revised: 7/2024 Cardinal Health 110, LLC. DBA Leader