

SENNOSIDES- sennosides tablet
Medline Industries

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.

682 Sennosides Laxative

Active ingredient (in each tablet)

Sennosides 8.6 mg

Purpose

Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 6-12 hours

Warnings

Do not use

- 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 or older | 2 tablets once a day | 4 tablets twice a day |
| children 6 to under 12 years | 1 tablet once a day | 2 tablets twice a day |
| children 2 to under 6 years | 1/2 tablet once a day | 1 tablet twice a day |
| children under 2 years | ask a doctor | ask a doctor |

Other information

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

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose*, liquid paraffin*, magnesium stearate, maltodextrin*, microcrystalline cellulose, mineral oil*, polyethylene glycol*, polyvinyl alcohol*, silicon dioxide*, sodium lauryl sulfate*, stearic acid*, talc*

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-800-MEDLINE (633-5463) Monday-Friday 9AM-5PM CST**

Principal Display Panel

†Compare to the active ingredient in Senokot®

SENNOSIDES

NATURAL VEGETABLE LAXATIVE INGREDIENT

Gentle, Overnight Relief of Constipation

Senosides, 8.6 mg


Tablets - 8.6 mg each

†This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot®.

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

Distributed by: Medline Industries, Inc., One Medline Place, Mundelein, IL 60060

NDC 53329-682-30




†Compare to the active ingredient in Senokot®

SENNOSIDES

NATURAL VEGETABLE LAXATIVE INGREDIENT

Gentle, Overnight Relief of Constipation



Sennosides, 8.6 mg

100 Tablets - 8.6 mg each

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each tablet) Purpose
Sennosides 8.6 mg.....Laxative


Uses ■ relieves occasional constipation (irregularity) ■ generally produces a bowel movement in 6 -12 hours

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■ stomach pain ■ nausea ■ vomiting
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***This product is not manufactured or distributed by Purdue Products L.P., distributor of Senokot®. Distributed by: Medline Industries, Inc. Mundelein, IL 60060 www.medline.com 1-800-Medline Re-order# OTC45101**



PLD-B22X
LB0003676
RC16PPL

8 **84389** 82336 4

Lot No.:
Exp. Date:

PEEL HERE →

Drug Facts (continued)

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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■ take preferably at bedtime or as directed by a doctor

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Monday-Friday 9AM-5PM CST

| | | | |
|--|--------------------------|---------------------------|-----------------|
| SENNOSIDES | | | |
| sennosides tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53329-682 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| SENNOSIDES (UNII: 3FYP5M0IUX) (SENNOSIDES - UNII:3FYP5M0IUX) | SENNOSIDES | 8.6 mg | |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |

| |
|---|
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |
| CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) |
| HYPROMELLOSES (UNII: 3NXW29V3WO) |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) |
| MINERAL OIL (UNII: T5L8T28FGP) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| TALC (UNII: 7SEV7J4R1U) |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |
| PARAFFIN (UNII: I9O0E3H2ZE) |
| POLYVINYL ALCOHOL (UNII: 532B59J990) |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--------------|
| Color | brown | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | S3;TCL080;S8 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53329-682-30 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/29/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 03/29/2016 | |

Labeler - Medline Industries (025460908)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|--|
| PLD Acquisitions LLC D/B/A Avema Pharma Solutions | | 804087794 | manufacture(53329-682) , pack(53329-682) |