

SENNA-S LAXATIVE- docusate sodium and sennosides tablet
New World Imports, Inc.

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.

Active ingredients (in each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses

- relieves occasional constipation (irregularity).
- generally causes bowel movement within 6 to 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
- a sudden change in bowel habits that lasts 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 the use of a laxative. These may indicate a serious condition.

If pregnant or breast-feeding, ask a health care 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

- taken preferably at bedtime or as directed by a doctor

| Age | Starting Dose | Maximum Dosage |
|---|----------------------|-----------------------|
| adults and children 12 years of age and older | 2 tablets once a day | 4 tablets twice a day |

| | | |
|-------------------------------------|-----------------------|-----------------------|
| children 6 to under 12 years of age | 1 tablet once a day | 2 tablets twice a day |
| children 2 to 6 years of age | 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: **sodium 6 mg/tablet** LOW SODIUM
- each tablet contains: **calcium 20 mg/tablet**
- store at 15°-30°C (59°-86°F), in well closed containers
- do not use if imprinted safety seal under cap is broken or missing
- *This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered trademark Senokot S.

Inactive ingredients

carnauba wax*, croscarmellose sodium, DandC Yellow 10 Aluminum Lake, dibasic calcium phosphate dihydrate, FDandC Blue 2 Aluminum Lake*, FDandC Red 40 Aluminum Lake*, FDandC Yellow 6 Aluminum Lake, hypromellose*, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol*, purified water*, sodium benzoate*, stearic acid, titanium dioxide

*may also contain

Product Labeling

NDC 51824-026-01

Compare to the active ingredients of Senokot-S®*

SENNA-S LAXATIVE

Natural Vegetable Laxative

Stool softener plus laxative

60 Docusate Sodium, 50 mg

Sennosides, 8.6 mg Tablets

You may report serious side effects to:

Distributed by

NWI, Inc 160 Athens Way

Nashville, TN 37228

Compare to the active ingredients in Senna-S[®]

Senna-S Laxative

Natural Vegetable Laxative

► Stool Softener Plus Laxative

For Gentle, Overnight Relief of Constipation

60 Docusate sodium, 50 mg
Sennosides, 8.6 mg Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredients (in each tablet) Purpose
Docusate Sodium 50 mg Stool softener
Sennosides 8.6 mg Stimulant laxative

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

Warnings
Do not use ■ this product if you are presently 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
■ a sudden change in bowel movements that persists over 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 could be signs of a serious condition.
If pregnant or breast-feeding, ask a health care professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued under label)

Distributed By:
Mylan Inc. 60 Miles Way
North Wales, PA 17058
LE11164
R0912

Lot No.:
Exp. Date:

0 85317 00561 0

PEEL HERE

Drug Facts (continued)

■ take preferably at bedtime or as directed by a doctor

| Age | Starting dosage | Maximum dosage |
|---------------------------------------|-----------------------|-----------------------|
| Adults and children 12 years and over | 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 20 mg, sodium 6 mg (LOW SODIUM)
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, D&C Yellow #10 aluminum lake, FD&C Yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide.

This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senna-S[®].

SENNAS-S LAXATIVE

docusate sodium, sennosides tablet

Product Information

| | | | |
|-------------------------|----------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:51824-026 |
| Route of Administration | ORAL | DEA Schedule | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------|-------------------|----------|
| DOCUSATE SODIUM (DOCUSATE) | DOCUSATE SODIUM | 50 mg |
| SENNOSIDES (SENNOSIDES) | SENNOSIDES | 8.6 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|----------|
| CARNAUBA WAX | |
| CROSCARMELOSE SODIUM | |
| D&C YELLOW NO. 10 | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE | |
| FD&C BLUE NO. 2 | |

| | |
|-----------------------------|--|
| FD&C RED NO. 40 | |
| FD&C YELLOW NO. 6 | |
| HYPROMELLOSES | |
| MAGNESIUM STEARATE | |
| CELLULOSE, MICROCRYSTALLINE | |
| POLYETHYLENE GLYCOLS | |
| POLYVINYL ALCOHOL | |
| WATER | |
| SODIUM BENZOATE | |
| STEARIC ACID | |
| TITANIUM DIOXIDE | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | TCL081 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------|----------------------|--------------------|
| 1 | NDC:51824-026-01 | 60 in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 12/01/2012 | |

Labeler - New World Imports, Inc. (075372276)

Revised: 12/2012

New World Imports, Inc.