**SENOKOT-S- standardized senna concentrate and docusate sodium tablet**
**Purdue Products LP**

*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.*

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***Senokot-S***
***(standardized senna concentrate and docusate sodium)***

***Drug Facts***

***Active ingredients (in each tablet)***

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

**Ask a doctor before use 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 | 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 10 mg, sodium 4 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***Inactive ingredients***

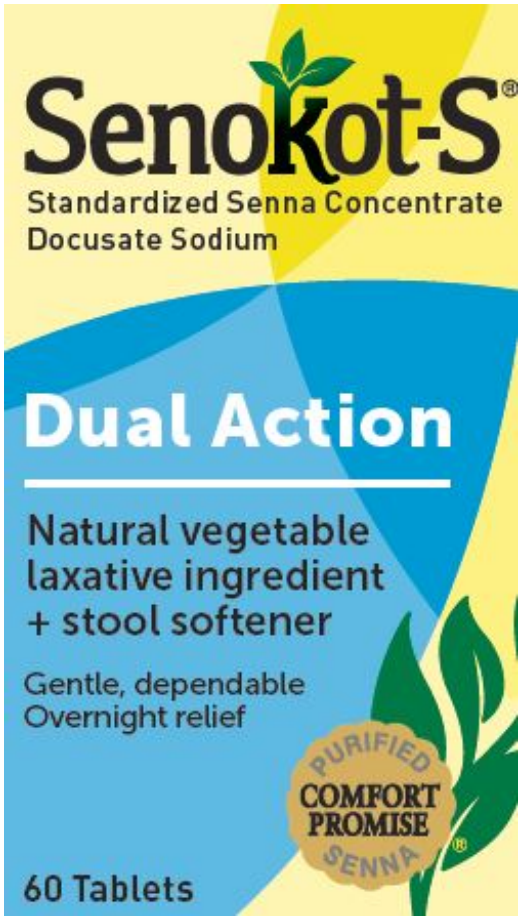
***Inactive ingredients*** Inactive ingredients dicalcium phosphate,D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium benzoate, talc, and titanium dioxide



Manufactured for:
**Purdue Products L.P.**
**Stamford, CT 06901-3431**
By:
**Purdue Pharma**
**575 Granite Court**
**Pickering, ON L1W 3W8, Canada**

**304221-0A**

Senokot-S 60 Tablets Carton
NDC: 67618-310-60




# SENOKOT-S

standardized senna concentrate and docusate sodium tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67618-310 |
| **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** |
| **CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS** (UNII: L11K75P92J) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **EGG PHOSPHOLIPIDS** (UNII: 1Z74184RGV) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOLS** (UNII: 3WQ0SDW1A) | |

| | |
|---|---|
| **POLYVINYL ALCOHOL** (UNII: 532B59J990) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | ORANGE | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | P |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67618-310-04 | 1 in 1 CARTON | 10/01/1974 | |
| **1** | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:67618-310-01 | 1 in 1 CARTON | 10/01/1974 | |
| **2** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **3** | NDC:67618-310-30 | 1 in 1 CARTON | 10/01/1974 | |
| **3** | | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **4** | NDC:67618-310-60 | 1 in 1 CARTON | 10/01/1974 | |
| **4** | | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part334 | 10/01/1974 | |

## Labeler - Purdue Products LP (141916531)

## Registrant - Purdue Pharma LP (932323652)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Purdue Pharma | | 250955291 | MANUFACTURE(67618-310) |

Revised: 3/2017 Purdue Products LP