**SENOKOTXTRA- standardized senna concentrate 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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***SenokotXTRA***
***(standardized senna concentrate)***

***Drug Facts***

***Active ingredient (in each tablet) Purpose***

Sennosides 17.2 mg

***Purpose***

Laxative

***Uses***

- relieves occasional constipation (irregularity)
- generally causes 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 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 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 | 1 tablet once a day | 2 tablets twice a day |
| children 6 to under 12 years | 1/2 tablet once a day | 1 tablet twice a day |
| children under 6 | ask a doctor | ask a doctor |

***Other information***

- each tablet contains: **calcium 20 mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***Inactive ingredients*** croscarmellose sodium, dicalcium phosphate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, mineral oil, stearic acid, talc, tartaric acid



Dist. by: **Purdue Products L.P., Stamford, CT 06901-3431**

302602-0A

SenokotXTRA

12 Tablets


# SENOKOTXTRA

standardized senna concentrate tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67618-315 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SENNOSIDES** (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) | SENNOSIDES | 17.2 mg |

| Inactive Ingredients |
|---|

| Ingredient Name | Strength |
|---|---|
| **croscarmellose sodium** (UNII: M28OL1HH48) | |
| **anhydrous lactose** (UNII: 3SY5LH9PMK) | |
| **magnesium stearate** (UNII: 70097M6I30) | |
| **cellulose, microcrystalline** (UNII: OP1R32D61U) | |
| **mineral oil** (UNII: T5L8T28FGP) | |
| **stearic acid** (UNII: 4ELV7Z65AP) | |
| **tartaric acid** (UNII: W4888I119H) | |
| **hypromelloses** (UNII: 3NXW29V3WO) | |
| **anhydrous dibasic calcium phosphate** (UNII: L11K75P92J) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BROWN (Light Brown) | **Score** | no score |
| **Shape** | ROUND | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | X |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67618-315-12 | 1 in 1 CARTON | 09/01/1988 | |
| **1** | | 12 in 1 BLISTER PACK | | |
| **2** | NDC:67618-315-36 | 3 in 1 CARTON | 09/01/1988 | 01/01/2014 |
| **2** | | 12 in 1 BLISTER PACK | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part334 | 09/01/1988 | |

## Labeler - Purdue Products LP (141916531)

## Registrant - Purdue Pharma LP (932323652)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Contract Pharmacal Corporation | | 968334974 | MANUFACTURE(67618-315) |

Revised: 2/2014 Purdue Products LP