

SENNA PLUS- senna plus tablet
Rebel Distributors Corp

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.

Senna Plus Drug Facts

Active ingredient

Sennosides from Senna Concentrate 8.6mg

Docusate Sodium 50mg

Purpose

Laxative & Stool Softener

Uses

For the short term relief of constipation. Produces bowel movement in 6 to 12 hours.

Warnings

Do not use ° for longer than one week ° when abdominal pain, nausea or vomiting are present.

Ask a doctor or pharmacist before use if you have noticed a sudden change in bowel habits that lasts over a period of two weeks.

Stop use and ask a doctor if ° you have rectal bleeding ° you fail to have a bowel movement after use of this product, this 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

° Take preferably at bedtime or as directed by a doctor ° if you do not have a comfortable bowel movement by the second day, increase dose by one table (do not exceed the maximum dosage) or decrease dose until you are comfortable.

Adults & children over 12 years: 2 tablets once a day (maximum dosage, 4 tablets twice a day)

Children 6 to under 12 years: 1 tablet once a day (maximum dosage, 2 tablets twice a day)

Children 2 to under 6 years: 1.2 tablet once a day (maximum dosage, 1 tablet twice a day)

Children under 2 years: do not use

Other Information

Store at room temperature, USP.

Inactive ingredients

Croscarmellose Sodium, Dicalcium Phosphate, FD&C Yellow No. 5, FD&C Yellow No. 6, Hypromellose, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Sodium Benzoate, Starch, Stearic Acid and Titanium Dioxide.

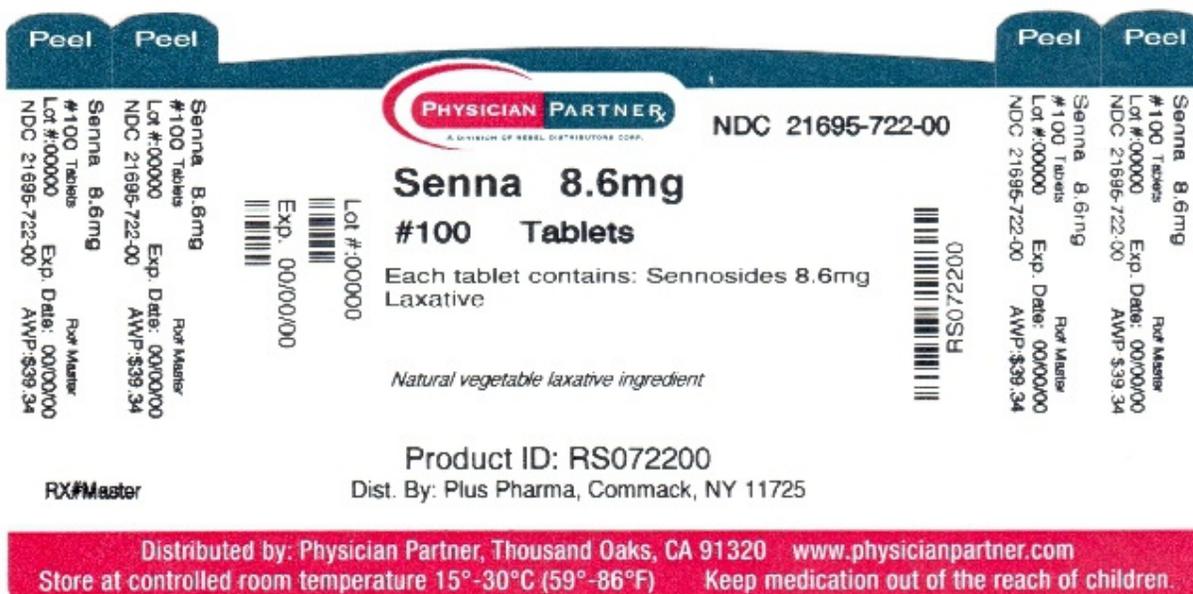
Distributed by: Plus Pharma

Commack, NY 11725

Repackaged by: Rebel Distributors Corp

Thousand Oaks, CA 91320

Package/Label Principal Display Panel



SENNA PLUS

senna plus tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21695-722(NDC:51645-851) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|--------------------|--------|
| SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES - UNII:3FYP5M0IJX) | SENNOSIDES A AND B | 8.6 mg |
|--|--------------------|--------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM SILICATE (UNII: 9B9691B2N9) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|--------|--------------|----------|
| Color | ORANGE | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | CPC490 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:21695-722-60 | 60 in 1 BOTTLE | | |
| 2 | NDC:21695-722-00 | 100 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 07/10/2009 | |

Labeler - Rebel Distributors Corp (118802834)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Rebel Distributors Corp | | 118802834 | RELABEL, REPACK |