**PROMOLAXIN- docusate sodium tablet**
**Proficient Rx 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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**Promolaxin™ Docusate Sodium Stool Softener**

**Active ingredient**

Docusate Sodium 100 mg

**Purpose**

Stool Softener

**Uses**

- for relief of occasional constipation (irregularity). This product generally produces a bowel movement within 12 to 72 hours.

**Warnings**

**Do not use**

- laxative products for longer than one week unless directed to do so by a doctor
- if you are presently taking mineral oil unless told to do so by a doctor

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding
- you fail to have a bowel movement after use
  These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a doctor before use.

**Keep out of Reach of Children.**

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

**Directions**

**Adults and children 12 years of age and older:**

Take 1 tablet as needed, not to exceed more than 3 tablets daily, or as directed by a doctor.

**Children under 12 years of age:**

Consult a doctor before use.

**Other information**

- Each tablet contains: **Calcium 40 mg**
- Each tablet contains: **Sodium 10 mg**
- Store at room temperature.
- Do not use if imprinted safety seal is broken or missing.

**Inactive ingredients**

Croscarmellose Sodium, Dicalcium Phosphate, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Silica, Sodium Benzoate, Stearic Acid.

**Questions?**

If you have any questions or comments, or to report an adverse event,

please contact 714-875-6316.

**Manufactured for:** Physician's Science and Nature, Inc.

220 Newport Center Drive 11-634, Newport Beach, CA 92660

**Repackaged by:** Proficient Rx LP, Thousand Oaks, CA 91320

**Package/Label Principal Display Panel**

Physician's Science and Nature, Inc.

NDC 63187-125-00

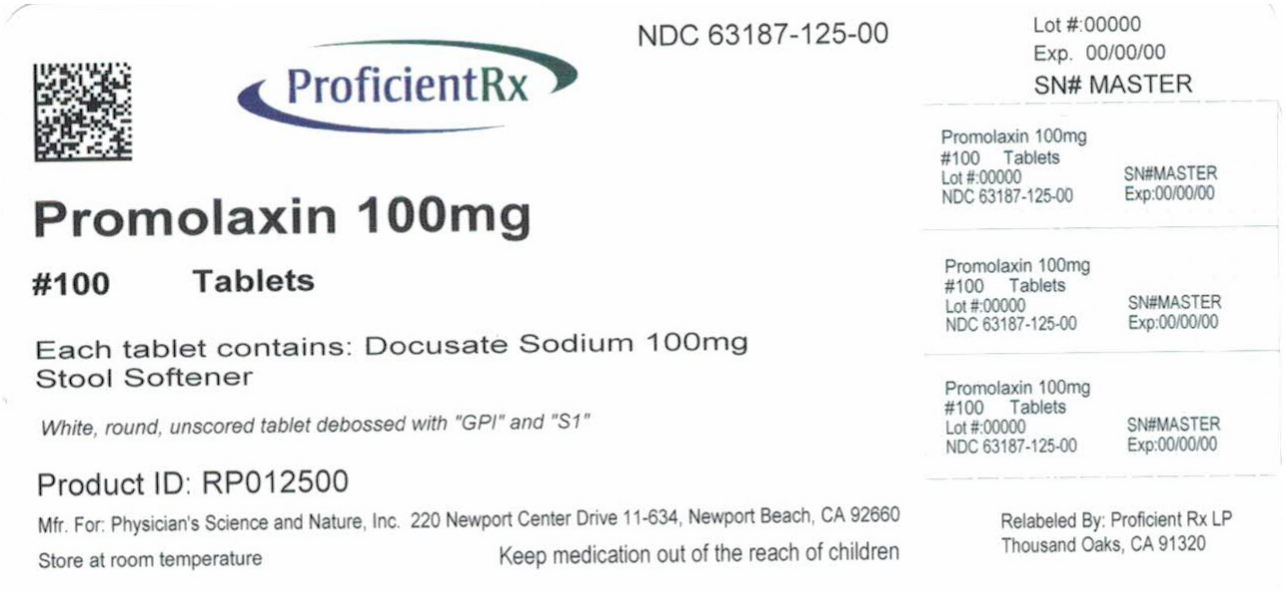
**Promolaxin™**

Docusate Sodium

Stool Softener

**100 mg Each**

**100 Tablets**




**Bottle Label**

Bottle Label

# PROMOLAXIN

docusate sodium tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63187-125(NDC:27495-012) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DOCUSATE SODIUM** (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 100 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **ANHYDROUS DIBASIC CALCIUM PHOSPHATE** (UNII: L11K75P92J) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | ROUND | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | GPI;S1 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63187-125-00 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part334 | 04/15/2011 | |

## Labeler - Proficient Rx LP (079196022)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Proficient Rx LP | | 079196022 | REPACK(63187-125) , RELABEL(63187-125) |

Revised: 1/2021 Proficient Rx LP