

## **STOOL SOFTENER STIMULANT LAXATIVE- docusate sodium and sennosides tablet**

### **QUALITY CHOICE (Chain Drug Marketing Association)**

*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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## **DRUG FACTS**

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

Docusate sodium 50 mg

Sennosides 8.6 mg

### **Purpose**

Stool softener

Stimulant laxative

### **Uses**

- for overnight relief from occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

### **Warnings**

#### **Do not use**

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are now 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 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 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 only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.

|  |                           |
|--|---------------------------|
| adults and children 12 years and older | take 2-4 tablets daily    |
| childrens 6 to under 12 years of age   | take 1-2 tablets daily    |
| children 2 to under 6 years of age     | take up to 1 tablet daily |
| children under 2                       | ask a doctor              |

### Other Information

- each tablet contains: **calcium 20 mg**
- each tablet contains: **sodium 6 mg** VERY LOW SODIUM
- store at 25°C(77°F), protect from heat, light, and moisture

### Inactive ingredients

carnauba wax\*, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, maltodextrin\*, microcrystalline cellulose, polyethylene glycol\*, polyvinyl alcohol\*, silicon dioxide, sodium benzoate\*, stearic acid, talc\*, titanium dioxide

\*contains one or more of these ingredients

### Questions or comments?

Call **1-248-449-9300 Monday-Friday 9AM-5PM EST**

### Principal Display Panel

†Compare to the Active Ingredients in Peri-Colace®

**STOOL SOFTENER** Plus Stimulant Laxative

Docusate sodium, 50 mg

Sennosides, 8.6 mg

Effective

Reliable

Comfortable

TABLETS

†This product is not manufactured or distributed by Purdue Products L.P., Distributor of Peri-Colace®.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**


Distributed by C.D.M.A. Inc.©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

**Product Label**



NDC 63868-135-10


‘Compare to the active ingredients in Peri-Colace’

# Stool Softener

## Plus Stimulant Laxative

Docosate Sodium, 50 mg  
Sennosides, 8.6 mg

Effective  
Reliable  
Comfortable



**100** Tablets

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

**Drug Facts**

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 Docosate sodium 50 mg.....Stool softener  
 Sennosides 8.6 mg.....Stimulant laxative

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**Drug Facts (continued under label)**

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 43157 W. Nine Mile  
 Novi, MI 48376-0995  
 www.qualitychoice.com  
 Questions: 248-449-9300



PLD-F6F 6 3551595235 5  
 Lot No.:  
 Exp. Date:

PEEL HERE →

**Drug Facts (continued)**

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**Questions or comments?**  
 Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

**Quality Choice Stool Softener Red Tablet**

**STOOL SOFTENER STIMULANT LAXATIVE**

docosate sodium and sennosides tablet

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63868-135 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>   | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| <b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM          | 50 mg           |
| <b>SENNOSIDES</b> (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)    | SENNOSIDES               | 8.6 mg          |

## Inactive Ingredients

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                        |                 |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                |                 |
| <b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP) |                 |
| <b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)                 |                 |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                       |                 |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |                 |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                        |                 |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)         |                 |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |                 |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                     |                 |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |                 |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                      |                 |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                 |                 |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)      |                 |

## Product Characteristics

|                 |       |                     |                    |
|-----------------|-------|---------------------|--------------------|
| <b>Color</b>    | red   | <b>Score</b>        | no score           |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 10mm               |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | TCL097;0806;AV;S44 |
| <b>Contains</b> |       |                     |                    |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:63868-135-10 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/30/2015                  | 05/31/2024                |

## Marketing Information

| <b>Marketing</b> | <b>Application Number or Monograph</b> | <b>Marketing Start</b> | <b>Marketing End</b> |
|------------------|--|------------------------|----------------------|
|------------------|--|------------------------|----------------------|

| Category                | Citation | Date       | Date       |
|-------------------------|----------|------------|------------|
| OTC monograph not final | part334  | 11/30/2015 | 05/31/2024 |

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2021

QUALITY CHOICE (Chain Drug Marketing Association)