

## **STOOL SOFTENER- docusate sodium capsule, liquid filled**

**CVS Pharmacy**

*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 ingredient (in each softgel)**

Docusate sodium 100 mg

#### **Purpose**

Stool softener laxative

#### **Uses**

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

#### **Warnings**

##### **Do not use**

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 or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

##### **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 or in divided doses.

|                                       |                         |
|---------------------------------------|-------------------------|
| adults and children 12 years and over | take 1-3 softgels daily |
| children 2 to under 12 years of age   | take 1 softgel daily    |
| children under 2 years                | ask a doctor            |

**Other information**

- **each softgel contains**:sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

**Inactive ingredients**

D&C red #33\*, D&C yellow #10\*, edible ink, FD&C blue #1\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin\*, medium-chain triglycerides\*, polyethylene glycol, propylene glycol\*, purified water, sorbitan, sorbitol, titanium dioxide

\*contains one or more of these ingredients

**Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Principal Display Panel**

Compare to the active ingredient in Colace®\*\*

**Stool Softener**

Docusate sodium, 100 mg

Relieves constipation

- Gentle stool softener
- Reliable relief

Softgels

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

\*\*This product is not manufactured or distributed by Purdue L.P, owner of the registered trademark Colace®

Distributed by: CVS pharmacy Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com

1-800-SHOP CVS

**Product Labeling**



Compare to the active ingredient in Colace® Stool Softener†

NDC 59779-038-01

# Stool Softener

DOCUSATE SODIUM 100 mg  
Relieves constipation

- Gentle stool softener
- Reliable relief
- Stimulant free



Actual Size

100 SOFTGELS

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### Drug Facts (continued under label)

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V-31418



Lot No.:

Exp. Date:



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**Drug Facts (continued)**  
movement after use of a laxative. These could be signs of a serious condition.  
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## CVS Stool Softener

### STOOL SOFTENER

docusate sodium capsule, liquid filled

#### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-038 |
| 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 |
|--------------------------------------|----------|
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)    |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |          |

|  |  |
|--|--|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)        |  |
| <b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)      |  |
| <b>GELATIN</b> (UNII: 2G86QN327L)                    |  |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                   |  |
| <b>EGG PHOSPHOLIPIDS</b> (UNII: 1Z74184RGV)          |  |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U) |  |
| <b>POLYETHYLENE GLYCOLS</b> (UNII: 3WJQ0SDW1A)       |  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)           |  |
| <b>WATER</b> (UNII: 059QF0K00R)                      |  |
| <b>SORBITAN</b> (UNII: 6O92ICV9RU)                   |  |
| <b>SORBITOL</b> (UNII: 506T60A25R)                   |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)           |  |

### Product Characteristics

|                 |            |                     |              |
|-----------------|------------|---------------------|--------------|
| <b>Color</b>    | RED, WHITE | <b>Score</b>        | no score     |
| <b>Shape</b>    | OVAL       | <b>Size</b>         | 12mm         |
| <b>Flavor</b>   |            | <b>Imprint Code</b> | P10;S78;SCU2 |
| <b>Contains</b> |            |                     |              |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59779-038-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:59779-038-03 | 30 in 1 BOTTLE; Type 0: Not a Combination Product  |                      |                    |
| 3 | NDC:59779-038-25 | 250 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 4 | NDC:59779-038-36 | 36 in 1 BOTTLE; Type 0: Not a Combination Product  |                      |                    |
| 5 | NDC:59779-038-40 | 400 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 6 | NDC:59779-038-75 | 750 in 1 BOTTLE; 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                                  | 07/30/2013           |                    |

### Labeler - CVS Pharmacy (062312574)