

## **STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled 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 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\*, edible ink, FD&C blue #1\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol\*, purified water, sorbitan, sorbitol, 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 ingredient in COLACE® Regular Strength Stool Softener

### Stool Softener

#### Laxative

Docusate Sodium 100 mg

For Relief Of:

Occasional Constipation

SOFTGELS

†This product is not manufactured or distributed by Purdue Product L.P., distributor of Colace® Regular Strength Stool Softener.

**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 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

# Product Label

NDC 63868-560-25

QC QUALITY CHOICE

\*Compare to the active ingredient in COLACE® Regular Strength Stool Softener

## Stool Softener

Laxative

Docusate Sodium 100 mg

For Relief Of:  
Occasional Constipation



250 Softgels

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

<b>Drug Facts</b>
<b>Active ingredient (in each softgel)</b> Docusate sodium 100 mg.....Stool softener laxative
<b>Uses</b> ■ relieves occasional constipation (irregularity) ■ generally produces bowel movement in 12 to 72 hours
<b>Warnings</b> Do not use if you are presently taking mineral oil, unless told to do so by a doctor.
<b>Ask a doctor before use if you have</b> ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks
<b>Stop use and ask a doctor if</b> ■ 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
<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.
<b>Directions</b> ■ 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
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<b>Questions or comments?</b> Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

PLD-DZL  
LB005044

Lot No.: 6 3551599631 1

Exp. Date:



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## QUALITY CHOICE Stool Softener Laxative

STOOL SOFTENER LAXATIVE			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-560
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)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6O92ICV9RU)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIOXIDE (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;SCU2;D1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-560-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2017	08/31/2024

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/31/2017	08/31/2024

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

Revised: 5/2023

QUALITY CHOICE (Chain Drug Marketing Association)