

**STOOL SOFTENER- docusate sodium capsule, liquid filled**  
**Shopko Stores Operating Co., LLC.**

*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 100mg

**Purpose**

Stool softener

**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 stool softener laxative for more than 1 week

**If pregnant or breastfeeding**

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.

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adults and children over 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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**Other information**

- **each softgel contains:** sodium 6 mg

- store at controlled room temperature 15° - 30° C (59°- 86° F)
- \*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®

### **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, sorbitol special, and titanium dioxide

### **Questions or comments?**

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

### **Principal display panel**

\*compare to colace® active ingredient

STOOL SOFTENER

Relieves occasional constipation

Docusate Sodium, 100 mg

safe, gentle & reliable

**DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

PACKAGED BY: PL Developments

200 hicks street

westbury NY 11590

### **Product Labeling**

**SHOPKO®** \*Compare to Colace® active ingredient

# Stool Softener

Relieves Occasional Constipation

**Docosate Sodium, 100 mg**

Safe, Gentle & Reliable



**100 Softgels**

Do not use if imprinted safety seal under cap is broken or missing.

**Drug Facts**

**Active ingredient (in each softgel)**  
Docosate Sodium 100 mg.....Stool softener

**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

**Drug Facts (continued under label)**

**Packaged by: PL Developments**  
**200 Hicks Street Westbury**  
**NY 11590, USA**

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By Return Or Exchange



PLD-B  
L01SHK100TT  
4 00201 58562 4

Lot No.:  
Exp. Date:

**PEEL HERE** →

**Drug Facts (continued)**

**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 stool softener 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
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children under 2 years	ask a doctor

**Other information** ■ each softgel contains: sodium 6 mg ■ store at controlled room temperature 15°-30°C (59°-86°F)  
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**Questions or comments?**  
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**Monday - Friday 9AM-5PM EST**

**Docosate sodium 100 mg**

## STOOL SOFTENER

docosate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:370 12-110
<b>Route of Administration</b>	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: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	RED (WHITE)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	P10;51A
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-110-01	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/09/2010	

**Labeler** - Shopko Stores Operating Co., LLC. (023252638)

Revised: 8/2012

Shopko Stores Operating Co., LLC.