## 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.

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

#### 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

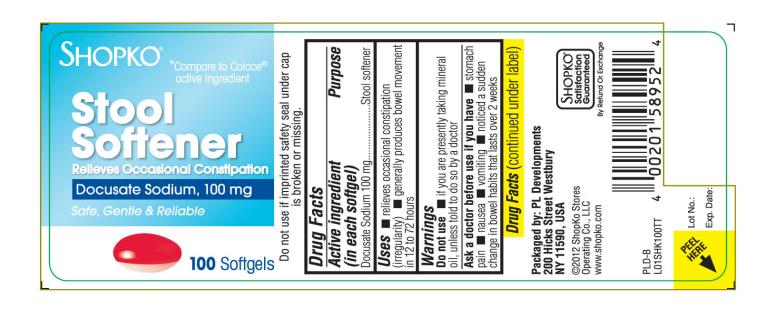
#### DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

PACKAGED BY: PL Developments

200 hicks street

westbury NY 11590

#### **Product Labeling**



contains: sodium 6 mg ■ store at controom 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® 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 *UITECTIONS* ■ Take only by mouth. Doses may be taken as a single daily dose or in divided professional before use. **Keep out of reach of children**. In case of overdose, get medical help Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special, Inactive ingredients D&C Red #33, edible ink, FD&C Blue #1, FD&C Red #40, FD&C children 2 to under 12 years of age adults and children 12 years and over or contact a Poison Control Center right away Monday- Friday 9AM-5PM EST Call toll free 1-877-753-3935 children under 2 years If pregnant or breast-feeding, ask a health softener laxative for more than 1 week serious condition. **Drug Facts** (continued Questions or comments? Other information you need to use a stool ask a doctor take 1 softgel daily take 1-3 softgels daily store at controlled each softge

#### Docusate sodium 100 mg

#### STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-110

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: PDC6 A3C0 OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
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.