

**STOOL SOFTENER- docusate sodium capsule, liquid filled**  
**Care One (American Sales Company)**

*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 capsule)**

Docusate Sodium 100 mg

**Purpose**

Stool softener

**Uses**

- for the prevention of dry, hard stools
- for relief of occasional constipation. This product generally produces a bowel movement within 12 to 72 hours.

**Warnings - Do not use**

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea or vomiting are present
- for longer than one week, unless directed by a doctor

**Ask a doctor before use if**

you notice a sudden change in bowel habits that persists over a period of 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding
- you fail to have a bowel movement after use

**If pregnant or breast-feeding,**

ask a health care 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**

- **adults and children 12 years and over:** take 1- 2 capsules preferably at bedtime
- **children 6 to 12 years of age:** take 1 capsule at bedtime

**Other information**

- **each capsule contains:** sodium 6 mg
- store at controlled room temperature 15° - 30° C (59°- 86° F)
- do not use if imprinted safety seal under cap is broken or missing.
- \*This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered trademark Colace®

## Inactive Ingredients

D&C Red #33, edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special and titanium dioxide. May also contain: FD&C blue #1 and purified water.

## Principal Display Panel

Compare to active ingredient of COLACE®\*

### stool softener

Docusate sodium 100 mg

**Distributed by: American Sales Company**

**4201 walden avenue, Lancaster, NY 14086**

## Product Label

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PLD 9/05  
L07C0250TT 3 4 1520 31405 6

Lot No.:  
Exp. Date:

### Docusate Sodium 100 mg

## STOOL SOFTENER

docusate sodium capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-115
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
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)	
SORBITOL (UNII: 506T60A25R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	

### 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:41520-115-25	1 in 1 BOX		
1		25 in 1 BOTTLE		
2	NDC:41520-115-10	100 in 1 BOTTLE		
3	NDC:41520-115-20	250 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/20/2010	

**Labeler** - Care One (American Sales Company) (809183973)

**Registrant** - P and L Development of New York Corporation (800014821)

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Care One (American Sales Company)