

**STOOL SOFTENER- docusate sodium capsule, liquid filled**  
**PuraCap Pharmaceutical 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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**STOOL SOFTENER**

**Drug Facts**

**Active ingredient (in each softgel)**

Docusate sodium 100 mg

**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 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 to 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 5 mg**
- **VERY LOW SODIUM**
- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

**Inactive ingredients**

Black ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special and purified water

**Questions or comments?**

Call toll free: **1-800-833-6278**

**Principal Display Panel**

STOOL SOFTENER

DOCUSATE SODIUM 100mg 100SOFTGELS

Compare to the active ingredient in COLACE®

NDC 51013-122-14



# STOOL SOFTENER

docusate sodium capsule, liquid filled

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:510 13-122

**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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	red, white (Two-Tone)	Score	no score
Shape	capsule (Oval)	Size	13mm
Flavor		Imprint Code	PC18
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-122-24	1 in 1 CARTON	06/01/2016	
1		100 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	06/01/2016	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-122) , analysis(51013-122)