

STOOL SOFTENER- docusate sodium capsule
BJWC (Berkley & Jensen / BJ's)

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.

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 1-3 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)

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: **1-800-934-1204 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient of COLACE®*

stool softener

Docusate sodium, 100 mg

Convenient & Predictable relief of constipation

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

***This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®**

Product Label

BERKLEY & JENSEN
CONSTIPATION RELIEF

STOOL SOFTENER
DOCUSATE SODIUM, 100 mg
CONVENIENT & PREDICTABLE RELIEF OF CONSTIPATION

Compare to the active ingredient of Colace®*

400 | 100
SOFTGELS | MG EACH

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Quality Guaranteed
Distributed by B&JWC
25 Research Drive
Westborough, MA 01581

PLD-A LB000865
4 00006 88099 4

Lot No.:
Exp. Date:

Docusate Sodium 100 mg

STOOL SOFTENER

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6839-1-110
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
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: 059QF0K00R)	

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:68391-110-04	400 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	06/10/2013	

Labeler - BJWC (Berkley & Jensen / BJ's) (159082692)**Registrant** - P and L Development of New York Corporation (800014821)