

STOOL SOFTENER- docusate sodium capsule, liquid filled
P & L Development, 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.

Drug Facts

Active Ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told 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 laxative for more than 1 week

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

- 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 25° C (77° F); excursions permitted between 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, sorbitan, sorbitol, titanium dioxide

*Contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

stool softener

docusate sodium 100 mg

stool softener laxative

softgels

†Compare to the active ingredient in Colace® Regular Strength Stool Softener

†This product is not manufactured or distributed by Purdue Product L.P., distributor of Colace® Regular Strength Stool Softener.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label



wb
wellness basics

stool softener
docusate sodium
100 mg
stool softener laxative
100 softgels

¹Compare to the active ingredient in Colace® Regular Strength Stool Softener

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each softgel) Purpose
Docusate sodium 100 mg.....Stool softener laxative

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)

¹This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

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



PLD-AZL 3 597262 23801 4
Lot No.: Exp. Date:
LB005391

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 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 25°C (77°F); excursions permitted between 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, sorbitan, sorbitol, titanium dioxide
*contains one or more of these ingredients

Questions or comments?
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

WELLNESS BASICS Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-078
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 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: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;SCU2;D1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-078-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2018	01/31/2025
2	NDC:59726-078-40	400 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2018	01/31/2025
3	NDC:59726-078-01	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2018	01/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/31/2018	01/31/2025

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023

P & L Development, LLC