

**STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
P & L Development, LLC**

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

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

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 (1-800-222-1222) 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 5 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

ammonium hydroxide, anhydrous citric acid, D&C red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

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

Principal Display Panel

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

Stool Softener

docusate sodium 100 mg

stool softener laxative

softgels

†This product is not manufactured or distributed by Avrio Health 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

*Compare 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)
This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

Actual Size

PLD-8705A
LB008215
3 59726 23801 4
Lot No.: _____ Exp. Date: _____

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 (1-800-222-1222) 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 5 mg
■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients ammonium hydroxide, anhydrous citric acid, D&C Red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

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

WELLNESS BASICS Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-141
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: PDC6A3C0OX)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
WATER (UNII: 059QF0KO0R)
SORBITAN (UNII: 6O921CV9RU)
SORBITOL (UNII: 506T60A25R)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
ALCOHOL (UNII: 3K9958V90M)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
MINERAL OIL (UNII: T5L8T28FGP)
AMMONIA (UNII: 5138Q19F1X)
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)

Product Characteristics

Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	PC18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-141-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
2	NDC:59726-141-01	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
3	NDC:59726-141-40	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	12/31/2020	

Labeler - P & L Development, LLC (800014821)