

STOOL SOFTENER LAXATIVE- 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 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 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

black iron oxide, D&C red #33, edible ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, hypromellose, polyethylene glycol, 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

- gentle
- dependable
- stimulant-free

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



NDC 59726-852-10

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

stool softener

docusate sodium 100 mg stool softener laxative

- gentle
- dependable
- stimulant-free

100 softgels



actual size

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



3 59726 28583 4

PLD-F717A
LB008243

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 6 mg
■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients black iron oxide, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

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

READYinCASE Stool Softener Laxative

STOOL SOFTENER LAXATIVE			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-852
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: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-852-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
2	NDC:59726-852-01	1000 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 not final	part334	12/31/2020	

Labeler - P & L Development, LLC (800014821)

Revised: 12/2022

P & L Development, LLC