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 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

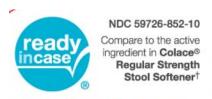
†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace Regular Strength Stool Softener.

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



stool softener

docusate sodium 100 mg stool softener laxative

- aentle
- dependable
- stimulant-free

100 softgels



actual size

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Questions or comments?

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Do not use if you are presently taking mineral oil, unless told to do so by a doctor

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■ noticed a sudden change in bowel habits that lasts over Ask a doctor before use if you have 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

of a serious condition.

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Drug Facts (continued)

Exp. Date:

Lot No.:

pregnant or breast-feeding, ask a health professional

medical help or contact a Poison Control Center

Keep out of reach of children. In case of overdose, get

(1-800-222-1222) right away

Directions

daily dose or in divided doses

take only by mouth. Doses may be taken as a single

you need to use a laxative for more than 1 week

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

READYinCASE Stool Softener Laxative

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each softgel contains: sodium 6 mg

Other information

children under 2 years

ask a doctor

children 2 to under

take 1 softgel daily

12 years and over adults and children

take 1-3 softgels daily

12 years of age

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: 2G860N327L)		

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
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
NDC:59726- 852-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
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 Drug	M007	12/31/2020	

Labeler - P & L Development, LLC (800014821)

Revised: 4/2024 P & L Development, LLC