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

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# **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<br/>take 1-3 softgels daily<br/>children 2 to under 12 years of age<br/>children under 2 yearstake 1 softgel daily<br/>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

#### **Principal Display Panel**

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

#### stool softener

docusate sodium 100 mg

stool softener laxative

#### Softgels

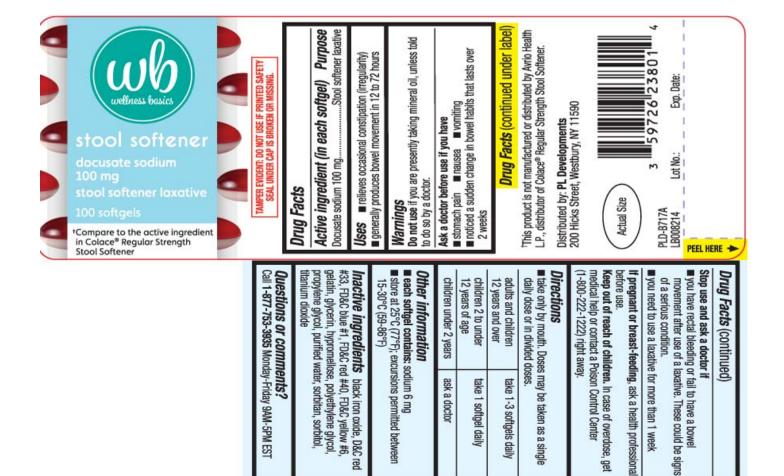
†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace Regular Strength Stool Softener.

# 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



#### WELLNESS BASICS Stool Softener Laxative

Re

take 1-3 softgels daily

ask a doctor

take 1 softgel daily

STOOL SOFTENER LA	ΔΧΔΤΙVΕ					
docusate sodium capsule, liq						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) ND		NDC:597	DC:59726-853	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingredient Name Basis of Streng			rength	Strength		
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM		DIUM	100 mg			
Inactive Ingredients						
	Ingredient Name			S	trength	
D&C RED NO. 33 (UNII: 9DBA0SB	B0L)					
FD&C BLUE NO. 1 (UNII: H3R47K3	3TBD)					
FD&C RED NO. 40 (UNII: WZ B912	7XOA)					
FD&C YELLOW NO. 6 (UNII: H77)	/EI93A8)					
GELATIN (UNII: 2G86QN327L)						

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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

# **Product Characteristics**

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

### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726- 853-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
2	NDC:59726- 853-01	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	
3	NDC:59726- 853-40	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug M	1007	12/31/2020	

# Labeler - P & L Development, LLC (800014821)

Revised: 4/2024

P & L Development, LLC