STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Publix Supermarkets, Inc.

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

Inactive ingredients

ammonium hydroxide, anhydrous citric, 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

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 HealthL.P., distributor of Colace® Regular Strength Stool Softener.

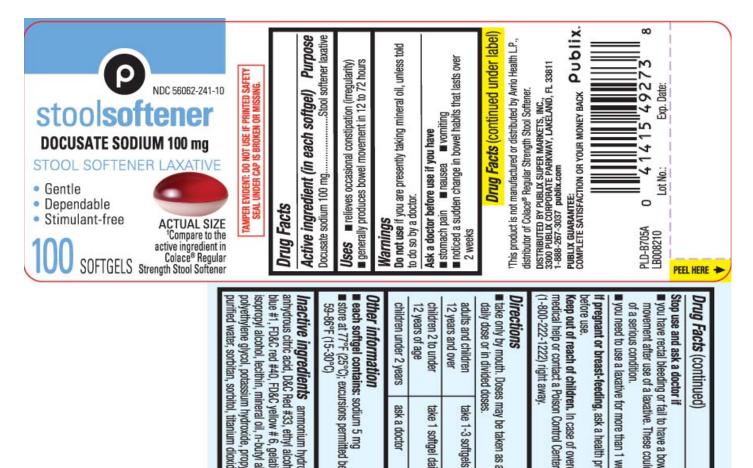
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,

3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811

1-888-267-3037

Product Label



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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 ourified water, sorbitan, sorbitol, titanium dioxide inactive ingredients ammonium hydroxide,

children under 2 years children 2 to under 12 years and over adults and children daily dose or in divided doses 12 years of age ask a doctor take 1 softgel daily take 1-3 softgels daily

(1-800-222-1222) right away. take only by mouth. Doses may be taken as a single Directions

Keep out of reach of children. In case of overdose, get you need to use a laxative for more than 1 week i pregnant or breast-feeding, ask a health professional of a serious condition.

you have rectal bleeding or fail to have a bowe movement after use of a laxative. These could be signs

PUBLIX Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-241
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)	
AMMONIA (UNII: 5138Q19F1X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

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

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:56062- 241-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2021	
	2	NDC:56062- 241-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/26/2021	

Labeler - Publix Supermarkets, Inc. (006922009)