STOOL SOFTENER- docusate sodium capsule, liquid filled Family Dollar (FAMILY WELLNESS)

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 right away.

Directions

• Take only by mouth. Doses may be taken as a single daily does 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

D&C red #33, edible ink, FD&C blue #1**, FD&C red #40, FD&C yellow #6, gelatin, glycerin, 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

For Comfortable Relief

SOFTGELS

*This product is not manufactured or distributed by Purdue Products 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: MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Product Labeling

^{**}contains one or more of these ingredients



FAMILY WELLNESS Stool Softener Laxative

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-578 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)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics			
Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;SCU2;D1
Contains			

l	P	Packaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:55319- 578-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2017	06/30/2025

Marketing Information			
Marketing Application Number or Monogra Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/30/2017	06/30/2025

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023 Family Dollar (FAMILY WELLNESS)