

**STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Sam's West, 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 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

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

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

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

stool softener laxative

docusate sodium 100 mg

gentle/effective

Stimulant-free

for comfortable relief

SOFTGELS

†This product is not manufactured or distributed by Purdue Products LLP., distributor of Colace® Regular Strength Stool Softener.

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

DISTRIBUTED BY:

SAM'S WEST, INC

BENTONVILLE, AR 72716

Product Label



Drug Facts
Active ingredient (in each softgel) Docusate sodium 100 mg..... Stool softener laxative
Uses <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces bowel movement in 12 to 72 hours
Warnings <p>Do not use if you are presently taking mineral oil, unless told to do so by a doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> stomach pain nausea vomiting <p>noticed a sudden change in bowel habits that lasts over 2 weeks</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
Directions <p>Take only by mouth. Doses may be taken as a single daily dose or in divided doses.</p> <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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, pepsin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide *contains one or more of these ingredients
Questions or comments? Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

¹This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

100% MONEY BACK GUARANTEE
SUPERIOR QUALITY AND PERFORMANCE
 We would like to hear from you with any comments or suggestions. In the continental U.S. or Canada, you can call us at 1-877-753-3935 from 9:00 a.m. to 5:00 p.m. EST Monday-Friday.



DISTRIBUTED BY:
 SAMS WEST, INC.
 BENTONVILLE, AR 72716
 PLD-B2L
 LB05064
 Lot No.: 0 1178742109136 5

MEMBER'S MARK Stool Softener Laxative

STOOL SOFTENER LAXATIVE			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-578
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)		
	SORBITAN (UNII: 6O921CV9RU)		

SORBITOL (UNII: 506T60A25R)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-578-60	600 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	09/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/30/2018	09/30/2025

Labeler - Sam's West, Inc (051957769)

Revised: 5/2023

Sam's West, Inc