### 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.

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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 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

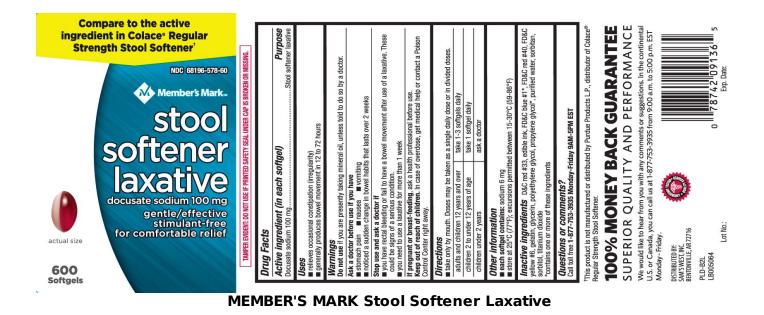
†This product is not manufactured or distributed by Purdue Products LLP., distributor of Colace® Regular Strength Stool Softener.

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

DISTRIBUTED BY:

SAM'S WEST, INC

# Product Label



STOOL SOFTENER L	ΑΧΑΤΙνε					
docusate sodium capsule, li	quid filled					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:681	NDC:68196-578	
Route of Administration	ORAL					
Active Ingredient/Active	e Moiety					
Ing	<b>Basis of Strength</b>		Strength			
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)			DOCUSATE SODIUM		100 mg	
Inactive Ingredients						
	Ingredient Name			S	trength	
D&C RED NO. 33 (UNII: 9DBA05	3B0L)					
FD&C BLUE NO. 1 (UNII: H3R47k	(3TBD)					
FD&C RED NO. 40 (UNII: WZ B91	27XOA)					
FD&C YELLOW NO. 6 (UNII: H77	VEI93A8)					
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL, UNSP	PECIFIED (UNII: 3WQ0SDW	1A)				
PROPYLENE GLYCOL (UNII: 6DC	9Q167V3)					
WATER (UNII: 059QF0KO0R)						
SORBITAN (UNII: 6092ICV9RU)						

	06T60A2					
TITANIUM DIOXID	E (UNII: 1	15FIX9V2JP)				
Due duet Cherm		-+:				
Product Chara						
Color	r	ed, white	Score		no score	
Shape	C	DVAL	Size		12mm	
Flavor			Imprint Code		P10;SCU2;D1	
Contains						
Packaging						
# Item Code		Package Desc	scription Market		Start	Marketing End
				Date		Date
1 NDC:68196-		BOTTLE, PLASTIC; Typ ation Product	e 0: Not a	09/30/2018		09/30/2025
NDC:68196-			e 0: Not a			
1 NDC:68196- 578-60	Combina	ation Product	e 0: Not a			
NDC:68196-	Combina	ation Product	e 0: Not a			
1 NDC:68196- 578-60	Combina	ation Product	or Monograph			
1 NDC:68196- 578-60 Marketing Marketing	Combina Infor A	mation Product mation pplication Number Citatio	or Monograph	09/30/2018 Marketing S	Start	09/30/2025 Marketing End

Labeler - Sam's West, Inc (051957769)

Revised: 5/2023

Sam's West, Inc