

DOCUSATE SODIUM - docusate sodium capsule

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

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 stool softener 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 softgel daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- **each capsule contains: sodium 5 mg Very Low Sodium**
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F). Keep tightly closed.

Inactive ingredients

D&C Red No.33, gelatin, glycerin, Neelicert FD&C Red No.40, Neelicert FD&C Yellow No.6, noncrystallizing sorbitol solution, polyethylene glycol, propylene glycol, purified water, shellac glaze, titanium dioxide.

Questions or Comments?

Call 1-855-274-4122 (toll-free)

(Monday - Friday 8:30 AM to 5:00 PM EST)

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®.

**DISTRIBUTED BY
SAM'S WEST, INC.
BENTONVILLE, AR 72716**

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 100 mg (600 Capsules Container Label)

**Compare to Colace®
active ingredient***

NDC 68196-995-64

Member's Mark™

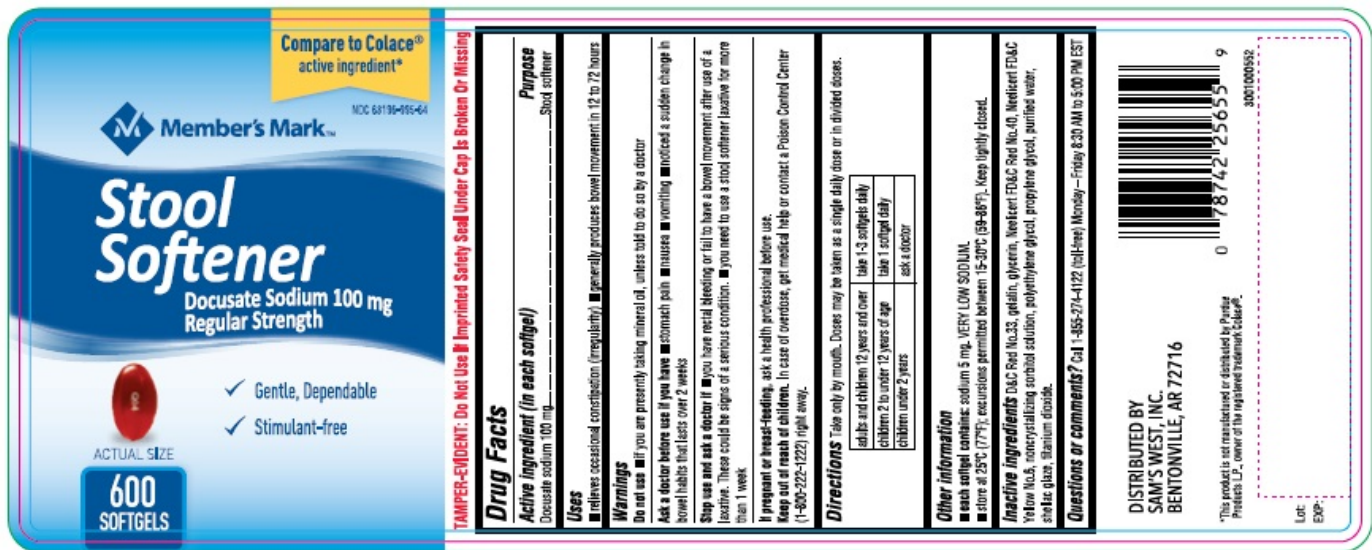
**Stool
Softener**

Docusate sodium 100 mg

Regular Strength

- Gentle, Dependable
- Stimulant-free

600 Softgels



DOCUSATE SODIUM			
docusate sodium capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-995
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)			
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)			
GLYCERIN (UNII: PDC6A3C0OX)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SORBITOL (UNII: 506T60A25R)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0K00R)			
SHELLAC (UNII: 46N107B710)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
Product Characteristics			
Color	RED	Score	no score
Shape	OVAL	Size	13mm

Flavor		Imprint Code	Q04	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-995-64	600 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	02/08/2018		

Labeler - Sam's West Inc (051957769)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	MANUFACTURE(68196-995)

Revised: 12/2020

Sam's West Inc