STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled The Kroger Co.

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
- 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 overtake 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?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient of COLACE® REGULAR STRENGTH STOOL SOFTENER **See back panel

Stool Softener

Docusate Sodium 100 mg

STOOL SOFTENER LAXATIVE

Gentle, Dependable

Stimulant-Free

SOFTGELS

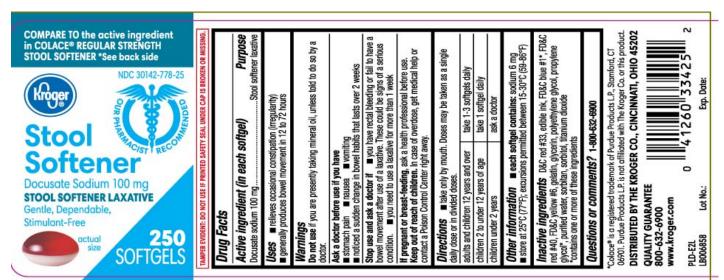
**Colace® is a registered trademark of Purdue Products L.P., Stamford, CT 06901. Purdue Products L.P. is not affiliated with The Kroger Co. or this product.

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

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

www.kroger.com

Product Label



KROGER Stool Softener

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-778

Route of Administration ORAL

Active Ingredient/Active Moiety

retive ingredient/retive violety				
Ingredient Name	Basis of Strength	Strength		
DOCUSATE SODIUM (UNII: F0502T21A0) (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 DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics					
Color	RED, WHITE	Score	no score		
Shape	OVAL	Size	12mm		

Flavor	Imprint Code	P10;SCU2;D1
Contains		

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:30142-778-	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2017		
l	2 NDC:30142-778- 25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2017		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	10/31/2017		

Labeler - The Kroger Co. (006999528)

Revised: 11/2019 The Kroger Co.