

DOCUSATE SODIUM- docusate sodium capsule
Reliable-1 Laboratories LLC

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.

Docusate Sodium 100 mg

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 directed 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

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

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 stool softner 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

adults and children 12 years and over	take 1 - 3 softgels once daily or in divided doses
children 2 to under 12 years of age	1 softgel once daily
children under 2 years	ask a doctor

Other information

- each softgel contains: **sodium 7 mg**
- store at room temperature 15°-25°C (59°-77°F) and avoid excessive heat

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400 NF, purified water, sorbitol

Questions or comments? Call **516-341-0666** 8:30 am - 4:30 pm ET, Monday - Friday

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

*Reliable-1 Laboratories LLC is not affiliated with the owner of the trademark Colace®

Distributed by: **Reliable-1 Laboratories LLC Valley Stream, NY 11580**

www.reliable1labs.com

Made in Romania

NDC 69618-044-10

*Compare to the active ingredient in Colace®

Reliable-1™ LABORATORIES

Docusate Sodium 100 mg

STOOL SOFTENER LAXATIVE

1000 SOFTGELS

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RE02-01

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Made in Romania

Lot No. _____
Exp. Date _____

69618-044-10-4

Rev. 0217 3

DOCUSATE SODIUM

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-044
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-044-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	
2	NDC:69618-044-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2017	

Labeler - Reliable-1 Laboratories LLC (079718111)