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 divded 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: s odium 7 mg
- store at room temperature 15º-25ºC (59º-77ºF) 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

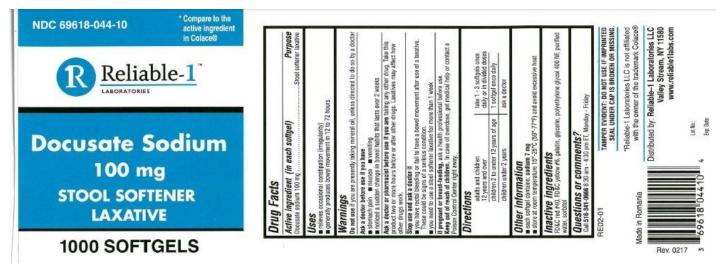
*Compare to the active ingredient in Colace®

Reliable-1[™] LABORATORIES

Docusate Sodium 100 mg

STOOL SOFTENER LAXATIVE

1000 SOFTGELS



DOCUSATE SODIUM docusate sodium capsule									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-044						
Route of Administration	ORAL								

A	tive Ingred	lient/Activ	<i>v</i> e Moiety						
Ingredient Name					Basis of Strength		Strengt		
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P271				JSATE - UNII:M7P27195	AG)	DOCUSATE SODIUM 100 mg			
In	active Ingr	edients							
			Ingredie	nt Name			Strength		
	ATER (UNII: 059								
	RBITOL (UNII: 5								
			(UNII: B6978949	SGQ)					
	&C RED NO. 4	-	-						
	YCERIN (UNII: P								
	&C YELLOW N		//VEI93A8)						
GE	LATIN (UNII: 2G	86QN327L)							
D,	roduct Char	actoristic	~ ~						
		acteristic	red	Score		20.6	core		
Color		OVAL	Size	no score 13mm					
Shape Flavor			OVAL				SCU1		
	ontains			Imprint Code		500	,,		
CU	intains								
Pa	ackaging								
#	ltem Code		Package De	scription	Marl	keting Start Date		eting End Date	
*	NDC:69618- 044-01	Combination			03/01/	2017			
	NDC:69618- 044-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			03/01/2017				
Μ	arketing	Inform	ation						
		ication Numb Citat					eting End Date		
	C monograph n			03/01/2017					

Labeler - Reliable-1 Laboratories LLC (079718111)

Revised: 8/2022

Reliable-1 Laboratories LLC