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 bowel movement after use of a laxative. These could be sings 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 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

- each softgel contains: **sodium 5 mg**

- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive ingredients

citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special and white edible ink

Questions or comments ?

Call **516-341-066** 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®

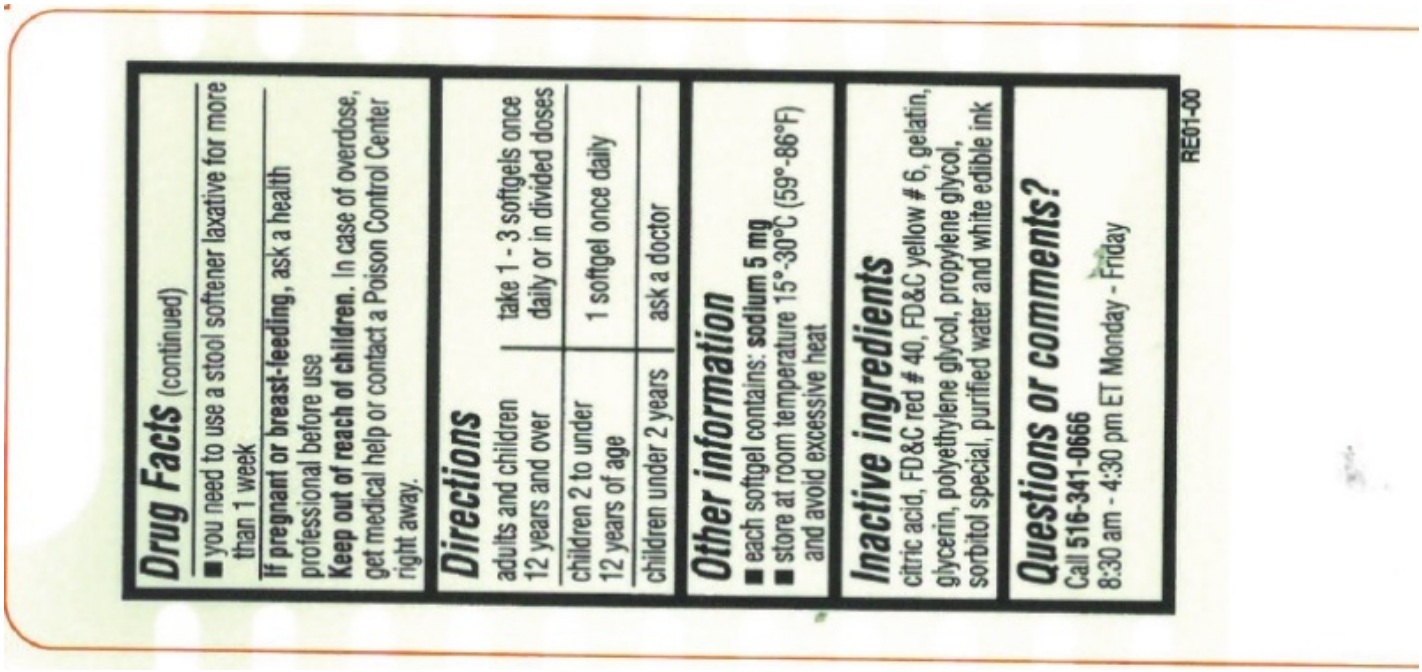
Distributed by: **Reliable-1 Laboratories LLC Valley Stream, NY 11580 www.reliable1labs.com**

PRINCIPLINE DISPLAY PANEL - Bottle Label 100ct

NDC 69618-043-01

Docusate Sodium 100 mg 100 SOFTGELS

STOOL SOFTENER LAXATIVE



PRINCIPLINE DISPLAY PANEL - Bottle Label 1000ct

NDC 69618-043-10

Docusate Sodium 100 mg 1000 SOFTGELS

STOOL SOFTENER LAXATIVE

DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69618-043
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-043-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2016	
2	NDC:69618-043-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/01/2016	

Labeler - Reliable 1 Laboratories LLC (079718111)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(69618-043) , analysis(69618-043)

Revised: 11/2019 Reliable 1 Laboratories LLC