

STOOL SOFTENER- docusate sodium capsule, liquid filled

Freds 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 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 over	take 1 to 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 controlled room temperature 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, sorbitol special, and titanium dioxide

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Stool Softener

Docusate Sodium 100 mg

Compare to the active ingredient in: Colace®*

Softgels

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

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Product Labeling

fred's NDC 55315-110-01

Stool Softener
 Docusate Sodium
 100 mg

Actual Size

100 Softgels

LAB TESTED
 Lab Tested for Quality, Fred Tested for Satisfaction

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Drug Facts (continued under label)

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 www.fredsinc.com

fred's Promise
 Not Happy With This Product?
 Just Bring It Back for a Refund!

PLD-C 0 84579 24232 0
 L01FR100

Lot No.:
 Exp. Date:

PEEL HERE

Drug Facts (continued)
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Fred's Stool Softener two-tone Softgel

STOOL SOFTENER			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-110
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)			
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED, WHITE	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	P10;51A
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-110-01	100 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/01/2010	

Labeler - Freds Inc (005866116)

Registrant - P and L Development of New York Corporation (800014821)