

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 laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are

presently taking mineral oil.

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using a laxative. These could be sign of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health care 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 with a glass of water

adults and children 12 years of age and over	take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.
children 2 to under 12 years of age	take 1 softgel daily

Other information

- **each softgel contains:** sodium 7mg
- store at 25°C (77°); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, medium-chain triglycerides*, polyethylene glycol, propylene glycol*, purified water sorbitan, sorbitol

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Stool Softener

Docusate Sodium, 100mg

Gentle Relief

Dependable Relief of Occasional Constipation

SOFTGELS

Compare to the active ingredient in: Dulcolax® Stool Softener†

†This product is not manufactured or distributed by Boehringer Ingelheim Consumer Health Care Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc., and owner of the registered trademark Dulcolax®.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Product Label

Exp. Date:
Lot No.:
F0002501
PLD-C10H



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Drug Facts (continued)

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children 2 to under 12 years
take 1 softgel daily
of age
children under 2 years
ask a doctor

Freds Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-244
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
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)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51;S77;SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-244-25	1 in 1 BOX	04/30/2015	
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	04/30/2015	

Labeler - Freds Inc (005866116)