STOOL SOFTENER- docusate sodium capsule, liquid filled Safeway, 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

- relieves occasional constipation (irregularity)
- generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told 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 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 only by mouth. Doses may be taken as a single daily dose or in divided doses.

Adults and children 12 years and over	take 1-3 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 25° C (77° F); excursions permitted between 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, sorbitan, sorbitol, titanium dioxide

*Contains one or more of these ingredients

Principal Display Panel

Compare to Colace® Regular Strength Stool Softener active ingredient

STOOL SOFTENER

DOCUSATE SODIUM 100 mg in each Softgel

Stool Softener Laxative

- Gentle
- Dependable
- Stimulant-free

SOFTGELS

†This product is not manufactured or distributed by Purdue Product L.P., distributor of Colace® Regular Strength Stool Softener.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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BETTER LIVING BRANDS LLC

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NDC 21130-578-60



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Ouestions or comments?

Call 1-888-723-3929 Monday-Friday 7AM-6PM PST

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Scan here for more information

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Lot / Exp.:

FC004633

Product of:

SIGNATURE CARE Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-578

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 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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

Product Characteristics				
Color	red, white	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	P10;SCU2;D1	
Contains				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:21130-578-	1 in 1 BOX	07/08/2013	02/28/2025		
1	60 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/08/2013	02/28/2025

Labeler - Safeway, Inc. (009137209)

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