

**STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Care One (American Sales Company)**

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 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
- a sudden change in bowel habits that lasts over 14 days

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 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

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener†

STOOL SOFTENER LAXATIVE

Docusate Sodium 100 mg

SOFTGELS

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

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

DISTRIBUTED BY FOODHOLD U.S.A., LLC

LANDOVER, MD 20785 •-877-846-9949

Product Label



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

Drug Facts
Active ingredient (in each softgel) Docosate sodium 100 mg.....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 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 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 ■ take only by mouth. Doeses 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, pectatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide *contains one or more of these ingredients
Questions or comments? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Parulac Products L.P., distributor of Colace® Regular Strength Stool Softener. S-949

1016

DISTRIBUTED BY
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
1-877-846-9949
© 2018 S&S Brands, LLC
Quality guaranteed or your money back.

PLJ-D2L LB005059 Lot No.: 3 41520 31405 6
Exp. Date:

CAREONE Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-779
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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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
1	NDC:41520-779-10	1 in 1 BOX	09/30/2018	12/27/2024
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41520-779-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2018	12/27/2024
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	09/30/2018	12/27/2024	

Labeler - Care One (American Sales Company) (809183973)

Revised: 10/2022

Care One (American Sales Company)