STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Care One (Retail Business Services, LLC.)

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 (1-800-222-1222) 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

black iron oxide, D&C Red #33, FD&C blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Principal Display Panel

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

STOOL SOFTENER LAXATIVE

Docusate Sodium 100 mg

SOFTGELS

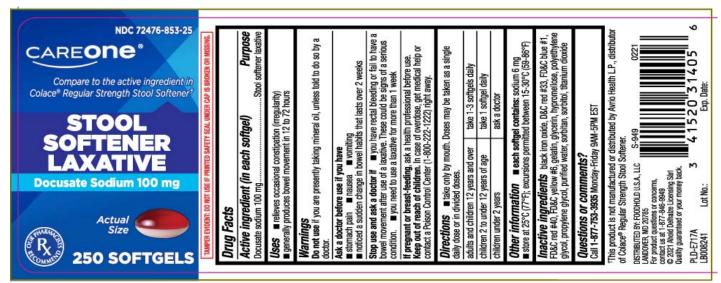
†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

Product Label



CAREONE Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-853
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10
Contains			

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72476- 853-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	
	2	NDC:72476- 853-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	03/26/2021	

Labeler - Care One (Retail Business Services, LLC.) (967989935)

Revised: 3/2024 Care One (Retail Business Services, LLC.)