

**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.*

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**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 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 with a glass of water

adults and children 12 years 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 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

**Inactive ingredients**

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

\*may contain 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 DulcoEase® Stool Softener

STOOL SOFTENER LAXATIVE

Docusate Sodium 100 mg

FAST, DEPENDABLE RELIEF OF OCCASIONAL CONSTIPATION

Softgels

†This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of DulcoEase®.

**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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**Product Labeling**

NDC 41520-684-25  
Compare to the active ingredient in  
DulcoEase® Stool Softener<sup>1</sup>

**CAREone®**

**STOOL SOFTENER LAXATIVE**  
Docusate Sodium 100 mg

FAST, DEPENDABLE RELIEF  
OF OCCASIONAL CONSTIPATION

Actual Size 

**25 SOFTGELS**

**CAREone®**  
**STOOL SOFTENER LAXATIVE**  
Docusate Sodium 100 mg  
FAST, DEPENDABLE RELIEF  
OF OCCASIONAL CONSTIPATION  
**25 SOFTGELS**

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION.  
TAMPER EVIDENT. DO NOT USE IF PRINTED SAFETY SEAL  
UNDER CAP IS BROKEN OR MISSING.

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P10-D101 F0004469

Lot No.:  
Exp. Date:

This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of DulcoEase®.  
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Questions or comments?**

**Inactive ingredients** edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitan, sorbitol  
\*contains one or more of these ingredients

**Other information**  
■ each softgel contains sodium 6 mg  
■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

**Drug Facts (continued)**

adults and children	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
children under 2 years	ask a doctor

**Directions** ■ take with a glass of water

**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 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.

**Uses**  
■ for temporary relief of occasional constipation and irregularly  
■ this product generally produces bowel movement in 12 to 72 hours

**Active ingredient (in each softgel)**  
Docusate sodium 100 mg.....Stool softener laxative

**CAREONE Stool Softener Laxative Softgels**

## STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-684
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)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	ORANGE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51;SCU1;D2
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-684-25	1 in 1 BOX	12/31/2017	
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	12/31/2017	

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

Revised: 10/2019

Care One (American Sales Company)