

STOOL SOFTENER- docusate sodium capsule, liquid filled
Cardinal Health (Leader) 70000

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
- 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. 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

Stool Softener Laxative

Docusate Sodium 100 mg

Gentle, Dependable

Stimulant-Free for

Comfortable Relief

SOFTGELS

COMPARE TO COLACE® REGULAR STRENGTH STOOL SOFTENER active ingredient**

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

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

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Product Label



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Exp. Date:

Cardinal Health®

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D181M, OHIO 43071

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Lot No.:

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0365
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: 059QF0K00R)	
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:70000-0365-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2018	
2	NDC:70000-0365-2	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2018	
3	NDC:70000-0365-3	750 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2018	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part334	06/30/2018	

Labeler - Cardinal Health (Leader) 70000 (097537435)

Revised: 11/2019

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