

STOOL SOFTENER EXTRA STRENGTH- 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 250 mg

Purpose

Stool softener laxative

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless directed by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last 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

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- **each softgel contains:** sodium 15 mg
- store at 20-25°C(68°-77°F); excursions permitted between 15-30°C (59°-86°F)

Inactive Ingredients

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

*may contain this ingredient

Questions or comments?

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

Principal Display Panel

Extra Strength

Stool Softener Laxative

Docusate Sodium, 250 mg

Stimulant-Free

Relieves Occasional Constipation

SOFTGELS

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 1-800-200-6313

Product Label

LEADERTM

NDC 70000-0385-1

**Extra Strength
Stool Softener
Laxative**

Docosate Sodium, 250 mg

Stimulant-Free
Relieves Occasional Constipation



Actual Size

**100% Money
Back Guarantee**

500 SOFTGELS

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

Drug Facts	Purpose
Active ingredient (in each softgel) Docosate sodium 250 mg	Stool softener laxative
Uses <ul style="list-style-type: none"> ■ for the prevention of dry, hard stools ■ for relief of occasional constipation ■ this product generally produces a bowel movement within 12 to 72 hours 	
Warnings <ul style="list-style-type: none"> Do not use if you are presently taking mineral oil, unless directed by a doctor. Ask a doctor before use if you have <ul style="list-style-type: none"> ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ 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 	
Directions <ul style="list-style-type: none"> ■ adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor ■ children under 12 years of age: ask a doctor 	
Other information <ul style="list-style-type: none"> ■ each softgel contains: sodium 15 mg ■ store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F) 	
Inactive ingredients edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special may contain this ingredient.	
Questions or comments? Call 1-877-753-8835 Monday-Friday 9AM-5PM EST	

Cardinal HealthTM
DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43007
www.myleader.com 1-800-200-6313
Essential to CareSM since 1979

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REV. 9/18
CIN 5450168
0 96295 13494 0

PLD-A210C Lot No.:
LE005824

Exp. Date:

LEADER Extra Strength Stool Softener Laxative

STOOL SOFTENER EXTRA STRENGTH

docosate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0385
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm

Flavor		Imprint Code	P20;SCU1	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0385-1	500 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 - Cardinal Health (Leader) 70000 (063997360)

Revised: 10/2022

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