

**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.*

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**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.**

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DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

## Product Label



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

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<b>Active ingredient (in each softgel)</b> Docusate sodium 250 mg	Stool softener laxative
<b>Uses</b> ■ for the prevention of dry, hard stools ■ for relief of occasional constipation ■ this product generally produces a bowel movement within 12 to 72 hours	
<b>Warnings</b> Do not use if you are presently taking mineral oil, unless directed by a doctor. <b>Ask a doctor before use if you have</b> ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks <b>Stop use and ask a doctor if</b> ■ 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 <b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
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✓ All LEADER® Brand Products Have A  
100% Money Back Guarantee  
Return to place of purchase if not satisfied.

Exp. Date:

PLD-A210C  
LB009824 Lot No.:

**LEADER Extra Strength Stool Softener Laxative**

# STOOL SOFTENER EXTRA STRENGTH

docusate 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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	09/30/2018	

**Labeler** - Cardinal Health (Leader) 70000 (097537435)

