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

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

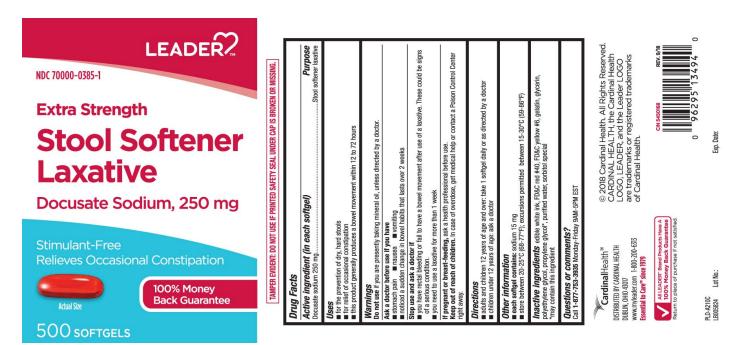
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

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

Product Label



^{*}may contain this ingredient

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		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
l	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: PDC6 A3C0 OX)		
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	20 mm
Flavor		Imprint Code	P20;SCU1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0385-	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		

Revised: 11/2019