

STOOL SOFTENER- docusate calcium capsule, liquid filled
P & L Development, LLC

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 calcium 240 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

if you are currently 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 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

- 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

- store at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn oil, D&C red #33*, edible white ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6*, gelatin, glycerin, purified water, sorbitol special

*contains 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 Surfak®†

Stool Softener

Docusate calcium 240 mg

Gentle Relief of Constipation

Take once a day

Softgels

†This product is not manufactured or distributed by Chatterm, Inc., distributor of Surfak®.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

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

Product Label

NDC 59726-257-01

Compare to the active ingredient in Surfak®†

ready incase™

stool softener

docusate calcium 240 mg

gentle relief of constipation

take once a day

100 softgels

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PLD-C209A
LB001716

Lot No.:
3 59726 28710 4

Exp. Date:

QUALITY
FIRST
EXCELLENCE

ReadyInCase Stool Softener Softgel

STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-257
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE CALCIUM	240 mg

Inactive Ingredients

Ingredient Name	Strength
CORN OIL (UNII: 8470G57WFM)	
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)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	RED	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P58;SCU
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-257-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	04/30/2014	

