

**STOOL SOFTENER- docusate calcium capsule, liquid filled
Rugby Laboratories, Inc.**

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 240mg

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 breastfeeding

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 between 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 and 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 240mg

Gentle Relief of Constipation

Take Once a Day

Softgels

**This product is not manufactured or distributed by Chattem, Inc., distributor of Surfak®

This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

Distributed by: Rugby Laboratories

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

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

Product Label



NDC 0536-1065-10

Compare to the active ingredient in Surfak®**

Stool Softener

Docusate calcium 240 mg

Gentle Relief of Constipation
Take Once a Day

1000 Softgels



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Drug Facts
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Questions or comments? Call 1-877-753-3955 Monday-Friday 9AM-5PM EST

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Re-order No. 370410
Rev. 09/16 R-58
1500 R1214E
PLD-F209B
LB001710



3 0536 106510 2

Exp. Date:

Lot No.:

Rugby Stool Softener

STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1065
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 RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K0OR)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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:0536-1065-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2015	
2	NDC:0536-1065-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2015	
3	NDC:0536-1065-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/31/2015	

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 6/2020

Rugby Laboratories, Inc.