

**DOCUSATE CALCIUM- docusate calcium capsule, liquid filled**  
**Central Texas Community Health Centers**

*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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**Docusate calcium**

**Active ingredient (in each softgel)**

Docusate Calcium 240 mg

**Purpose**

Stool softener

**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
- when abdominal pain, nausea, or vomiting are present
- for longer than 1 week, unless directed by a doctor

**Ask a doctor before use if**

you notice a sudden change in bowel habits that persists over a period of 2 weeks.

**Stop use and ask a doctor if**

- you have rectal bleeding
- you fail to have a bowel movement after use

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health care 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 over 12 years of age:** take 1 softgel daily for several days, or until bowel movements are normal, or as directed by a doctor
- **children under 12 years of age:** take as directed by a doctor

**Other information**

- store between 15°-30°C (59°-86°F)

**Inactive ingredients**

corn oil, D&C red #33, edible white ink, FD&C red #40, gelatin, glycerin, purified water and sorbitol special.

**Questions or comments?**

**1-800-645-2158**

**Principal Display Panel**

Compare to active ingredient in SURFAK®\*

Safe, Effective, Non-Habit Forming

Stool Softener Laxative DC

Docusate Calcium USP, 240 mg

SOFTGEL CAPSULES

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

**\*Rugby Laboratories is not affiliated with the owner of the trademark Surfak®.**

**Distributed by: Rugby Laboratories**

**31778 Enterprise Drive**

**Livonia, MI 48150**

**[www.rugbylaboratories.com](http://www.rugbylaboratories.com)**

**PRINCIPAL DISPLAY PANEL - 240 mg Capsule Bottle Label**

CommUnityCare Federally Qualified Health Centers

DOCUSATE

CALCIUM

240 MG

CAPS

Date:

Name:

Dr.

TAKE 1 CAPSULE BY MOUTH DAILY AS DIRECTED.

123456

1/1/01

DOCUSATE CA.240MG CAPS#30NDC 76413-307-30

Batch: 123456

Lot: 123456

Exp: 1/1/01

MAJOR

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

CommUnityCare Federally Qualified Health Centers

DOCUSATE  
CALCIUM  
240 MG  
CAPS

Date:

Name:

Dr.

TAKE 1 CAPSULE BY MOUTH DAILY AS DIRECTED.

TOME 1 CAPSULA POR BOCA DIARIA COMO INDICADO.

123456

1/1/01

DOCUSATE CA.240MG CAPS#30NDC 76413-307-30

Batch: 123456

Lot: 123456

Exp: 1/1/01

MAJOR

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**DOCUSATE CALCIUM**

docusate calcium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76413-307(NDC:0536-3755)
<b>Route of Administration</b>	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: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

<b>Color</b>	RED (RED)	<b>Score</b>	no score
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<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	8mm	
<b>Flavor</b>		<b>Imprint Code</b>	P58	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76413-307-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2011	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part334	12/01/2011		

**Labeler** - Central Texas Community Health Centers (079674019)

**Registrant** - P and L Development of New York Corporation (800014821)

### Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-307) , RELABEL(76413-307)

Revised: 3/2016

Central Texas Community Health Centers