

STOOL SOFTENER- 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.

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 - 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 76413-324-30

Batch: 123456

Lot: 123456

Exp: 1/1/01

SUNMARK

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 76413-324-30

Batch 123456

Lot: 123456

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STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-324(NDC:49348-122)
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	RED	Score	no score
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Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	P20;SCU
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-324-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/30/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/30/2014	

Labeler - Central Texas Community Health Centers (079674019)

Establishment			
Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-324) , RELABEL(76413-324)

Revised: 10/2016

Central Texas Community Health Centers