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 between 20-25ºC (68-77ºF); excursions permitted between 15-30ºC (59-86ºF)

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?

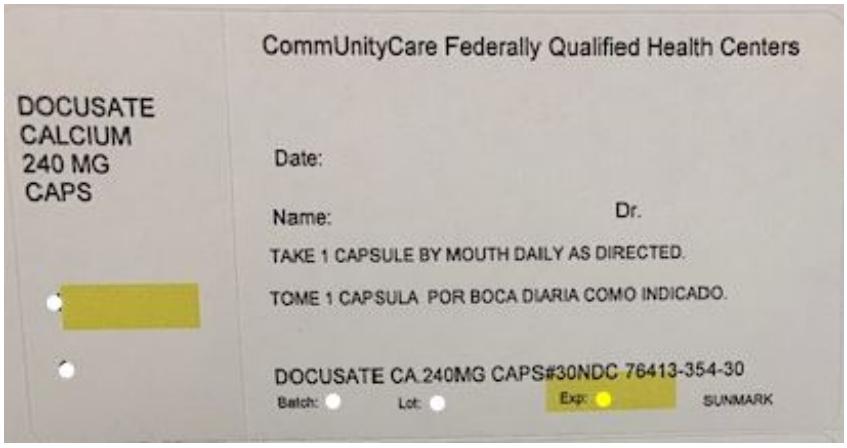
Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

HOW SUPPLIED

Product: 76413-354

NDC: 76413-354-30 30 CAPSULE, LIQUID FILLED in a BOTTLE, PLASTIC

STOOL SOFTENER (DOCUSATE CALCIUM) CAPSULE, LIQUID FILLED



STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-354(NDC:70677-0027)
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
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:76413-354-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/31/2017	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Travis County Healthcare District		797039398	RELABEL(76413-354) , REPACK(76413-354)

Revised: 11/2018 Central Texas Community Health Centers