

DOCUSATE CALCIUM 240 MG SODIUM FREE- docusate calcium capsule, liquid filled
National Vitamin Company

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.

Docusate Calcium 240 mg Sodium Free

Active ingredient

Docusate Calcium 240 mg

Purpose

Stool Softener

Uses

- For the relief of occasional constipation.
- Helps to prevent dry, hard stools.
- 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 one 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 two weeks.

Stop Use and Ask a Doctor If

- You have rectal bleeding.
- You fail to have a bowel movement after use.

If Pregnant or Breast Feeding

Ask a healthcare professional before use.

Keep Out of Reach of Children.

In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

Adults and Children over 12 years of age

Take orally 1 softgel daily for 2 to 3 days or until bowl movements are normal, or as directed by a

doctor.

Children under 12 years of age

Do not use this product for children under 12 years of age, unless directed by a doctor.

Other Information

- Keep lid tightly closed.
- Store at room temperature between 15°C to 25°C (59°F to 77°F).
- Do not use if either seal is broken or missing.

Inactive Ingredients

Corn Oil, FD&C Blue #1, FD&C Red #40, Gelatin, Glycerin, Ink (Edible), Sorbitol Special.

Questions or Comments

Call 1 (800) 682-9862

Package/Label Principal Display Panel

NDC 54629-0640-01

LIFE-LINE®

DOCUSATE

CALCIUM

SODIUM-FREE

STOOL SOFTENER

240 mg Each

100 Softgels

LIFE-LINE VITAMINS

U.S.A.

Since 1974

**Manufactured and Distributed by
NATIONAL VITAMIN COMPANY
Casa Grande, AZ 85122**

NDC 54629-0640-01

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Label

DOCUSATE CALCIUM 240 MG SODIUM FREE

docusate calcium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54629-640
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)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	NV02	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54629-640-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	02/01/2016		

Labeler - National Vitamin Company (102098324)

Registrant - National Vitamin Company (102098324)

Establishment

Name	Address	ID/FEI	Business Operations
National Vitamin Company		102098324	MANUFACTURE(54629-640) , ANALYSIS(54629-640)