# 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.

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## **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

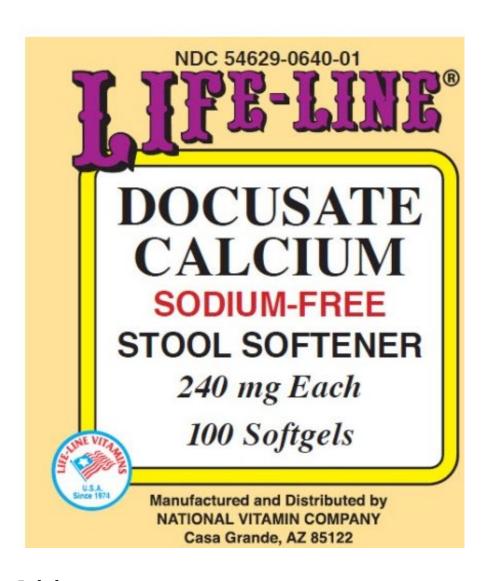
NDC 54629-0640-01

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



## Label

## **DOCUSATE CALCIUM 240 MG SODIUM FREE**

docusate calcium capsule, liquid filled

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|----------|-----|------|---------|---|
| Prod     | nct | Into | rmation | П |

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 |
|---|-------------------|----------|
| DO CUSATE 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                |      |              |          |  |

| l | Pa | ackaging                        |  |                      |                           |
|---|----|---------------------------------|--|----------------------|---------------------------|
| l | #  | # Item Code Package Description |  | Marketing Start Date | <b>Marketing End Date</b> |
| ı | 1  | NDC:54629-640-01                | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 0 2/0 1/20 16        |                           |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part334                                  | 0 2/0 1/20 16        |                    |  |
|                         |  |                      |                    |  |

## 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) |

Revised: 4/2020 National Vitamin Company