**DOCUSATE SODIUM- docusate sodium 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 Sodium, USP**
**Stool Softener**

**Active ingredient (*in each softgel*)**

Docusate Sodium 100 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 or you fail to have a bowel movement after use.

**If you are 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 right away.

**Directions**

| | |
|---|---|
| Adults and Children over 12 years of age | Take orally 1 to 2 softgels preferably at bedtime for 2-3 days or until bowel movements are normal, or as directed by a doctor. |
| Children 6 to 12 years of age | Take orally 1 softgel preferably at bedtime for 2-3 days or until bowel movements are normal, or as directed by a |

| | |
|---|---|
| | doctor. |
| Children under 6 years of age | Do not use this product for children under 6 years of age, unless directed by a doctor. |

**Other Information**

- **Each softgel contains 5 mg of Sodium.**
- Keep lid tightly closed.
- Store at room temperature between 15°C to 30°C (59°F to 86°F).
- Do not use if printed seal under cap is broken or missing.
- For identification purposes, each softgel will have an imprint that reads NV13.

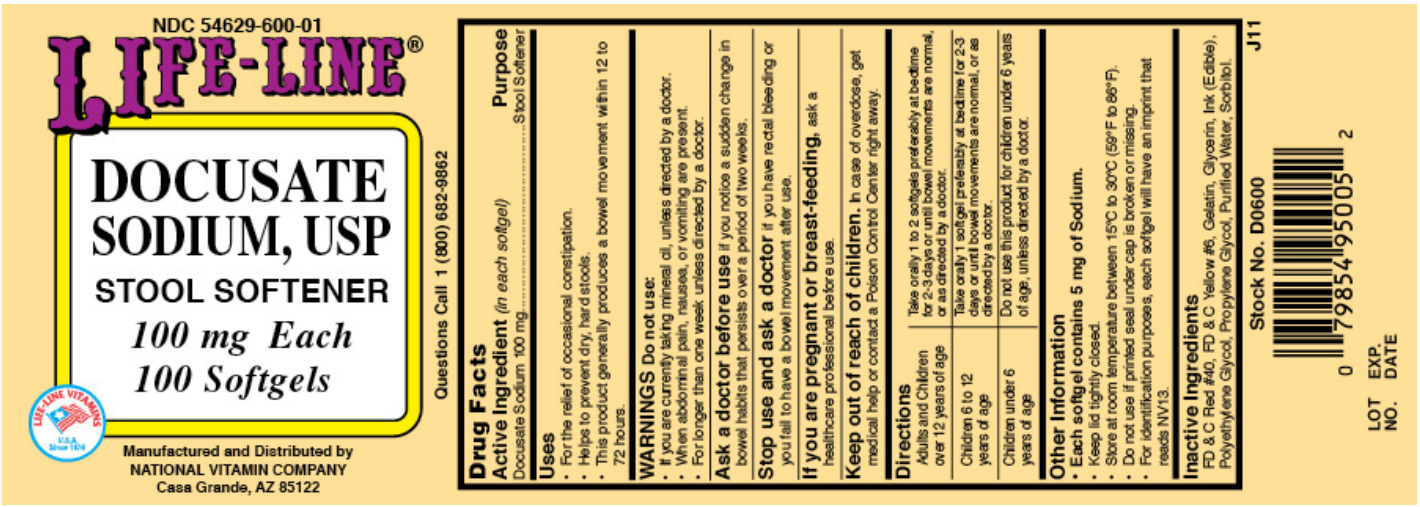
**Inactive ingredients**

FD&C Red #40, FD&C Yellow #6, Gelatin, Glycerin, Ink (Edible), Polyethylene Glycol, Propylene Glycol, Purified Water, Sorbitol.

**Package/Label Principal Display Panel**

**NDC 54629-600-01**
**Life-Line®**
**DOCUSATE SODIUM, USP**
**STOOL SOFTENER**
***100 mg Each***
***100 Softgels***

**Manufactured and Distributed by**
**National Vitamin Company**
**Casa Grande, AZ 85122**




**Bottle Label**

## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

**Product Information**

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:54629-600 |
| **Route of Administration** | ORAL | | |

| **Active Ingredient/Active Moiety** | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DOCUSATE SODIUM** (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) | DOCUSATE SODIUM | 100 mg |

| **Inactive Ingredients** | |
|---|---|
| **Ingredient Name** | **Strength** |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **GELATIN, UNSPECIFIED** (UNII: 2G86QN327L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLYETHYLENE GLYCOL 1000** (UNII: U076Q6Q621) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITOL** (UNII: 506T60A25R) | |

| **Product Characteristics** | | | |
|---|---|---|---|
| **Color** | RED | **Score** | no score |
| **Shape** | OVAL | **Size** | 12mm |
| **Flavor** | | **Imprint Code** | NV13 |
| **Contains** | | | |

| **Packaging** | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:54629-600-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2000 | |
| **2** | NDC:54629-600-99 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2000 | |

## Marketing Information

| **Marketing Category** | **Application Number or Monograph Citation** | **Marketing Start Date** | **Marketing End Date** |
|---|---|---|---|
| OTC monograph not final | part334 | 05/01/2000 | |

## Labeler - National Vitamin Company (102098324)

## Establishment

| **Name** | **Address** | **ID/FEI** | **Business Operations** |
|---|---|---|---|
| National Vitamin Company | | 102098324 | MANUFACTURE(54629-600) |

## Establishment

| **Name** | **Address** | **ID/FEI** | **Business Operations** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| SWISSCAPS Romania srl | | 565466997 | MANUFACTURE(54629-600) |