

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled  
NuCare Pharmaceuticals, Inc.**

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**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool Softener Laxative

**Uses**

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

**Warnings**

**Ask a doctor before use if you**

- have stomach pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

**Stop use and ask a doctor if**

- you need to use a laxative longer than 1 week
- you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition.

**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 and older: take 1-2 softgel daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

**Other information**

- **each softgel contains:** sodium 5 mg. very low sodium
- store at 15°C-25°C(59° F-77° F)
- keep tightly closed
- product from USA or Canada
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

### Inactive ingredients

FD and C red 40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. May also contain D and C yellow 10, FD and C yellow 6 (sunset yellow), mannitol.

### Package Label

**NuCare Pharmaceuticals, Inc.**

**Docusate Sodium 100mg**  
**Lot: 000000 NDC: 66267-0888-30**  
**MFR NDC: 57896-401-10 Exp.: 00-00**  
**Serial# 0000000002**

**NDC: 66267-888-30**  
**Docusate Sodium 100mg**  
**#30 Softgels**

Each softgel contains: Docusate Sodium 100mg.... Stool Softener Laxative FD&C yellow #6 (sunset yellow)  
 Warnings: Ask a doctor before use if you, have stomach pain, nausea or vomiting, have a sudden change in bowel habits that persists over a period of 2 weeks, are presently taking mineral oil. Stop use and ask a doctor if, you need to use a laxative longer than 1 week, you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition. 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. Oval Clear-Red Softgel Printed: "401"

**Distributed by:**  
**Gerri-Care Pharmaceuticals Corp.**  
**Brooklyn, NY 11204**

**Package by:**  
**NuCare Pharmaceuticals, Inc.**  
**Orange, CA 92867**

**STORAGE: CONTROLLED TEMPERATURE 59-77°F.**  
**WARNING: KEEP OUT OF REACH OF CHILDREN**  
 Call your doctor for medical advice about side effects.  
 You may report side effects to FDA at 1-800-FDA-1088.  
**Product #: P0888030GOV**

**GTIN 00366267888301**  
**Serial# 0000000002**  
**Exp. Date 00-00**  
**LOT#: 000000**

**PATIENT \_\_\_\_\_**  
**PROVIDER \_\_\_\_\_**  
**Docusate Sod. 100mg Softgels #30**  
**Take \_\_\_\_\_ softgel(s) every \_\_\_\_\_**  
**hours \_\_\_\_\_ times a day.**

**3 6 6 2 6 7 8 8 8 3 0 1**

## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66267-888(NDC:57896-401)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	

### Product Characteristics

<b>Color</b>	red (reddish)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	SCU1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66267-888-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
2	NDC:66267-888-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
3	NDC:66267-888-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
4	NDC:66267-888-91	120 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
5	NDC:66267-888-92	180 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/01/2000	

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

### Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(66267-888)