# 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

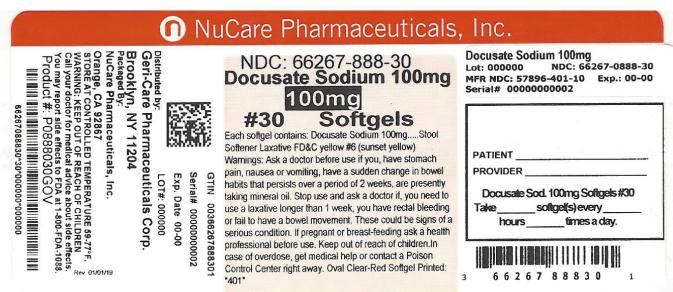
#### Other information

- 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



## **DOCUSATE SODIUM**

docusate sodium capsule, liquid filled

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

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

Inactive Ingredients	
Ingredient Name	Strength

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MANNITOL (UNII: 30WL53L36A)	

Product Characteristics				
Color	red (reddish)	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	SCU1	
Contains				

P	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)	