

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

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.

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.

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

Package By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Product #: P0888030GOV

Rev: 01/01/19

NDC: 66267-888-30
Docusate Sodium 100mg
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"

Docusate Sodium 100mg
 Lot: 000000 NDC: 66267-0888-30
 MFR NDC: 57896-401-10 Exp.: 00-00
 Serial# 00000000002

GTIN: 00366267888301 **Serial#:** 00000000002 **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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66267-888(NDC:57896-401)
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)	
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)				
MANNITOL (UNII: 3OWL53L36A)				
Product Characteristics				
Color	red (reddish)	Score no score		
Shape	OVAL	Size 12mm		
Flavor		Imprint Code SCU1		
Contains				
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 not final	part334	01/01/2000		

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

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