

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

gc 401

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

- do not exceed recommended dose
- adults and children 12 years and older: take 1-3 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by a doctor
- children under 12: consult a doctor

Other information

- **each softgel contains:** sodium 7 mg. Very low sodium
- store at 59°-77°F (15°-25°C)
- keep tightly closed
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

Inactive ingredients

FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerin, PEG, sorbitol special, water.

Package Label

NuCare Pharmaceuticals, Inc.

NDC: 68071-2874-0
Docusate Sodium 100mg
#100 Softgels
 See manufacturer's label for full list of ingredients.

Product #: R0744100

Docusate Sodium 100mg
 Lot: 00000 NDC: 68071-2874-00
 MFR NDC: 57896-401-01 Exp.: 00-00
 Serial# 0000000002

Docusate Sodium 100mg
 Lot: 00000 NDC: 68071-2874-00
 MFR NDC: 57896-401-01 Exp.: 00-00
 Serial# 0000000002

GTIN 00368071287400
 Serial# 0000000002
 Exp. Date 00-00
 LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Take _____ every _____ hours
 _____ times a day.

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Rev 01/01/19
 WARNING: KEEP OUT OF REACH OF CHILDREN
 STORE AT CONTROLLED TEMPERATURE 59-77°F.

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2874(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
GELATIN (UNII: 2G86QN327L)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
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:68071-2874-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2022	

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	relabel(68071-2874)

Revised: 5/2024

NuCare Pharmaceuticals, Inc.