STOOL SOFTENER- 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.

GC 401(408)

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&C red #40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. Also contains D&C yellow #10
or FD&C yellow #6 (sunset yellow).

Package Label

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-1656(NDC:57896-408)
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	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	A92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1656-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2018	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-1656)

Revised: 1/2022 NuCare Pharmaceuticals,Inc.