DOCUSATE SODIUM- docusate sodium capsule, liquid filled
American Health Packaging

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.

DOCUSATE SODIUM, USP
Stool Softener Laxative
Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation (irregularity)
- generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea or vomiting are present unless directed by a doctor
- for longer than one week unless directed by a doctor

Ask a doctor before use if you notice a sudden change in bowel habits that persists over a period of 2 weeks.

Stop use and ask a doctor if you have rectal bleeding or you fail to have a bowel movement after use of a laxative. This may indicate a serious condition.

If pregnant or breast-feeding, ask a health care 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

Take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years of age and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily

children under 2 years of age	ask a doctor

Other information

- **Each softgel contains:** sodium 7 mg VERY LOW SODIUM
- Store at room temperature between 15° to 30°C (59° to 86°F)
- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, Gelatin USP, Glycerin USP, Polyethylene Glycol 400 NF, Purified Water USP, Sorbital USP

The drug product contained in this package is from NDC # 61301-8001, SWISSCAPS Romania srl.

Distributed by:
American Health Packaging
2550 John Glenn Avenue, Suite A
Columbus, OH 43217

712901
0412901/0216PS

Principal Display Panel – Carton – 100 mg

NDC 60687-**129**-01

DOCUSATE SODIUM, USP Stool Softener Laxative

100 mg

100 Softgels (10 x 10)

(01) 0 03 60687 129 01 3

Drug Facts

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NDC 60687-**129**-01

DOCUSATE SODIUM, USP
Stool Softener Laxative

100 mg

100 Softgels (10 x 10)

Drug Facts (continued)

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The drug product contained in this package is from NDC # 61301-8001, SWISSCAPS Romania srl.

Packaged and Distributed by:
American Health Packaging
Columbus, Ohio 43217

712901
0412901/0119

NDC 60687- **129**-01

DOCUSATE SODIUM, USP
Stool Softener Laxative

100 mg

100 Softgels (10 x 10)

The drug product contained in this package is from
NDC # 61301-8001, SWISSCAPS Romania srl.

Packaged and Distributed by:
American Health Packaging
Columbus, OH 43217

712901
0412901/0119

Principal Display Panel - Blister – 100 mg

DOCUSATE SODIUM, USP
Stool Softener Laxative
Softgel **100 mg**

DOCUSATE SODIUM
docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60687-129
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

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:60687-129-01	100 in 1 BOX, UNIT-DOSE	10/27/2015	
1	NDC:60687-129-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/27/2015	

Labeler - American Health Packaging (929561009)

Revised: 9/2023 American Health Packaging