

DOCUSATE SODIUM 100MG- docusate sodium capsule
Pharmaceutica North America, Inc.

Active Ingredient

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a stool softener laxative for more than 1 week

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 (1-800-222-1222) 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 and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- **each softgel contains:** sodium 7 mg


- store at 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

Inactive Ingredients

citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special, white edible ink

Questions or comments? 1-888-788-6472

Product label



NDC 45861-0076-01

Docusate Sodium
Stool Softener Laxative
100mg Softgels

100 Softgels

Drug Facts

Active Ingredient (in each softgel)
Docusate Sodium 100mg.....Stool softener laxative

Uses

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Warnings

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Ask a doctor before use if you have ■ stomach pain

- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask doctor if ■ you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition. ■ you need to use a stool softener laxative for more than 1 week


If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Drug Facts (continued under label)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



Questions or comments? (888)788-6472

Manufactured For:
Pharmaceuticals North America, Inc.
Glendale, CA 91205

PEEL HERE ↘

Drug Facts (continued)

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

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**NO COPY
ADHESIVE ZONE**

DOCUSATE SODIUM 100MG

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45861-076
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 (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45861-076-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/01/2025	

Labeler - Pharmaceutica North America, Inc. (962739699)

Revised: 3/2025

Pharmaceutica North America, Inc.