

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

DRUG FACTS

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

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?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

docusate sodium

docusate sodium 100 mg


stool softener laxative

TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

Product Label

Drug Facts	
Active Ingredient (in each softgel)	Purpose
Docusate sodium 100mg....Stool softener laxative	
Uses	
<ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces bowel movement in 12 to 72 hours 	
Warnings	
Do not use if you are currently taking mineral oil, unless directed by a doctor	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> stomach pain - nausea - vomiting noticed a sudden change in bowel habits that lasts over 2 weeks 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> 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.	

NDC 72789-399-60



Docusate Sodium

Stool Softener Laxative

100 mg

Marketed and Package By:
PD-Rx Pharmaceuticals, Inc
Oklahoma City, OK 73127
1-405-942-3040 V.05.24.0

60 Softgels
TAMPER EVIDENT: DO NOT USE IF
SEAL IS BROKEN OR MISSING FROM BOTTLE.

Drug Facts (continued)	
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 of age	ask a doctor
Other information	
• each softgel contains: sodium 7 mg	
• store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F) • Keep tightly closed.	
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? call 1-877-753-3935 Monday-Friday 9AM-5PM EST	
	
GTIN: 00372789399607	
SNO: L22B69000006	
EXP: 07/2024	
LOT: L22B69	

DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72789-399(NDC:0904-7280)
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: 3WJQ05DW1A)	
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	CAPSULE (Oval)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-399-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2024	
2	NDC:72789-399-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	11/15/2022	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(72789-399)

Revised: 1/2025

PD-Rx Pharmaceuticals, Inc.