

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

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**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 last 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 a signs of a serious condition.
- you need to use a laxative for more than 1 week

**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 immediately (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 to 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 5 mg
- store at 25°C (77°F);excursions permitted between 15-30°C (59-86°F)

### **Inactive ingredients**

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitan, sorbitol

### **Questions or comments?**

Call **1-800-616-2471**

### **Principal Display Panel**

Docusate sodium 100 mg is a orange oval softgel with imprint P51.

NDC 72789-274-30 Bottles of 30 softgels.

Compare to the active ingredient in Colace ®Regular Strength Stool Softener†

Docusate sodium 100 mg

Stool Softener Laxative

Softgels


†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

### **Product Label**

Drug Facts	
<b>Active Ingredient</b> (in each softgel)	<b>Purpose</b>
Docusate sodium 100mg	Stool softener laxative
<b>Uses</b>	
<ul style="list-style-type: none"> <li>relieves occasional constipation (irregularity)</li> <li>generally produces bowel movement in 12 to 72 hours</li> </ul>	
<b>Warnings</b>	
Do not use if you are currently taking mineral oil, unless directed by a doctor	
<b>Ask a doctor before use if you have</b>	
<ul style="list-style-type: none"> <li>stomach pain, nausea or vomiting</li> <li>noticed a sudden change in bowel habits that lasts over 2 weeks</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.</li> <li>you need to use a stool softener laxative for more than 1 week</li> </ul>	
<b>If pregnant or breast feeding, ask a health professional before use.</b>	

NDC 72789-274-30



# Docusate Sodium

## Stool Softener Laxative

# 100 mg

Marketed and Package By:  
PD-Rx Pharmaceuticals, Inc  
Oklahoma City, OK 73127  
1-405-942-3040 V.11.19.0

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

Drug Facts (continued)	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center immediately (800) 222-1222 right away.	
<b>Directions:</b>	
• 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
<b>Other information</b>	
• each softgel contains: sodium 5 mg	
• store at (25°C) (77°F); excursions permitted between 15°- 30°C (59°- 86°F) • Keep tightly closed.	
<b>Inactive Ingredients:</b> edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol	
Questions or comments? call 1-800-616-2471	



GTIN: 00372789274300  
SNO: J22A99000003  
EXP: 10/2024  
LOT: J22A99

## DOCUSATE SODIUM

docusate sodium capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 72789-274(NDC:0904-6998)
<b>Route of Administration</b>	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)	
SORBITAN (UNII: 6O92ICV9RU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
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<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	P51
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-274-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/28/2020	

**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(72789-274)

Revised: 7/2024

PD-Rx Pharmaceuticals, Inc.