

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

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**Drug Facts**  
**Docusate Sodium**

**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool softener laxative

**Uses**

- for relief of occasional constipation (irregularity)
- this product 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 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.**

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

**Directions**

- take with a glass of water

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

### **HOW SUPPLIED**

For identification purposes, each orange softgel will have an imprint that reads P51.

NDC 72789-295-30 Bottles of 30 softgels.

NDC 72789-295-90 Bottles of 90 softgels.

### **Principal Display Panel**

Docusate Sodium


Stool Softener Laxative

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

### **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>for relief of occasional constipation irregularity</li> <li>this product generally produces bowel movement in 12 to 72 hours.</li> </ul>	
<b>Warnings</b>	
Do not use if you are presently 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>a sudden change in bowel habits that lasts more than 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>	
If pregnant or breast feeding, ask a health professional before use.	

NDC 72789-295-30



# Docusate Sodium

## Stool Softener Laxative

# 100 mg

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

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

Drug Facts (continued)	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (800)222-1222	
<b>Directions:</b>	
Take with a glass of water. This dose 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>	
<ul style="list-style-type: none"> <li>each softgel contains sodium 5 mg</li> <li>store at (25°C) (77°F); excursions permitted between 15° - 30°C (59° - 86°F)</li> </ul>	
<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 1-877-753-3935 Monday-Friday 9AM-5PM EST	



GTIN: 00372789295305  
SNO: L22B69000001  
EXP: 07/2024  
LOT: L22B69

## DOCUSATE SODIUM

docusate sodium capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72789-295(NDC:50804-862)
<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)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<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:72789-295-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/23/2022	
2	NDC:72789-295-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/23/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	05/28/2021	

**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(72789-295)

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.