

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

Docusate Sodium 100 mg Softgels

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

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 directed by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea or 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 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.

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

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
	take 1 softgel

children 2 to under 12 years of age	take 1 softgel daily
children under 2 years of age	ask a doctor

Other information

- **Tamper Evident: Do not use if seal is broken or missing from bottle**
- each softgel contains: **sodium 6 mg**
- **VERY LOW SODIUM**
- store at 25 °C (77 °F); excursions permitted between 15 °-30 °C (59 °-86 °F).

keep tightly closed.

Inactive ingredients

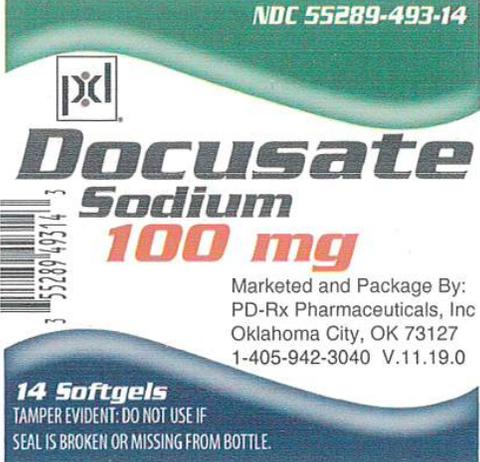
D&C Red #33, edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special

Questions?

Adverse drug event call: (866) 562-2756 Mon-Fri 8 AM to 4 PM

Docusate

Sodium

<p>Drug Facts</p> <p>Active Ingredient (in each softgel) Docusate Sodium 100mg.....Stool softener</p> <p>Purpose</p> <p>Uses</p> <ul style="list-style-type: none"> • relieves occasional constipation (irregularity) • generally produces bowel movement in 12 to 72 hours <p>Warnings</p> <p>Do not use if you are currently taking mineral oil, unless directed by a doctor</p> <p>Ask doctor before use if you have</p> <ul style="list-style-type: none"> • stomach pain, nausea or vomiting • noticed a sudden change in bowel habits that lasts over 2 weeks <p>Stop use and ask a doctor if</p> <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 <p>If pregnant or breast feeding, ask a health professional before use.</p>	<p style="text-align: right;">NDC 55289-493-14</p>  <p style="text-align: center;">Docusate Sodium 100 mg</p> <p>Marketed and Package By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 V.11.19.0</p> <p>14 Softgels TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately (800) 222-1222</p> <p>Directions:</p> <ul style="list-style-type: none"> • take only by mouth • Doses may be taken as a single daily dose or in divided doses <table border="1"> <tr> <td>Adults and children 12 years and over</td> <td>take 1-3 softgels daily</td> </tr> <tr> <td>Children 2 to under 12 years of age</td> <td>take 1 softgel daily</td> </tr> <tr> <td>Children under 2 years of age</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> • each softgel contains: sodium 6 mg • Very Low Sodium • store at (25°C) (77°F); excursions permitted between 15°- 30°C (59°- 86°F) • Keep tightly closed. <p>Inactive Ingredients: D&C Red # 33, edible ink, FD&C Red # 40, FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, titanium dioxide</p> <p>Questions or comments? (866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)</p> <p>GTIN: 00355289493143 SNO: L22C76000001 EXP: 07/2024 LOT: L22C76</p>	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
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DOCUSATE SODIUM

docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55289-493(NDC:16103-399)
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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color	red (Two-toned- white and clear red)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SCU2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-493-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2021	
2	NDC:55289-493-14	14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
3	NDC:55289-493-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
4	NDC:55289-493-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
5	NDC:55289-493-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
6	NDC:55289-493-93	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2023	
7	NDC:55289-493-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M007	03/01/2016	

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(55289-493)

Revised: 10/2025

PD-Rx Pharmaceuticals, Inc.