

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?

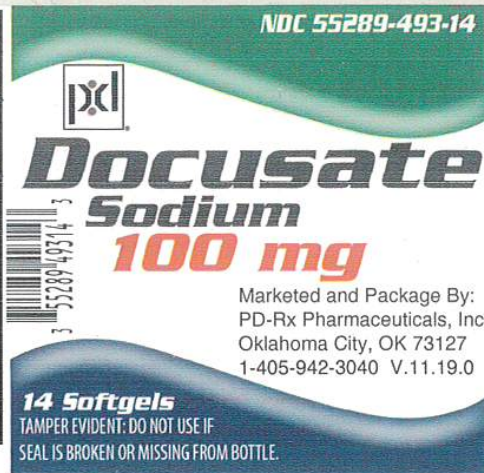
Adverse drug event call: (866) 562-2756 Mon-Fri 8 AM to 4 PM

Docusate

Sodium

| Drug Facts | |
|---|----------------------------------|
| Active ingredient (in each softgel) Docusate Sodium 100mg..... | Purpose Stool softener |
| 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 doctor before use if you have | |
| <ul style="list-style-type: none"> • stomach pain, nausea or 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 55289-493-14



Docusate Sodium 100 mg

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

14 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 immediately (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 |
| Children 2 to under 12 years of age | take 1 softgel daily |
| Children under 2 years of age | ask a doctor |
| Other information | |
| <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. | |
| 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 | |
| Questions or comments? (866) 562-2756 (Mon-Fri 8 AM to 4 PM EST) | |

GTIN: 00355289493143
SNO: L22C76000001
EXP: 07/2024
LOT: L22C76

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 |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| 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: 3/2024

PD-Rx Pharmaceuticals, Inc.