

STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Bryant Ranch Prepack

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

HOW SUPPLIED

Docusate Sodium 100 mg

- NDC: 71335-9731-1: 30 Capsules in a BOTTLE
- NDC: 71335-9731-2: 100 Capsules in a BOTTLE
- NDC: 71335-9731-3: 60 Capsules in a BOTTLE
- NDC: 71335-9731-4: 120 Capsules in a BOTTLE
- NDC: 71335-9731-5: 90 Capsules in a BOTTLE
- NDC: 71335-9731-6: 180 Capsules in a BOTTLE
- NDC: 71335-9731-7: 10 Capsules in a BOTTLE
- NDC: 71335-9731-8: 28 Capsules in a BOTTLE
- NDC: 71335-9731-9: 56 Capsules in a BOTTLE
- NDC: 71335-9731-0: 18 Capsules in a BOTTLE

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Docusate Sodium 100 mg Capsules



GTIN 003713597317
Lot 208820
Exp 9/16/2026
SN 0123456789

Drug Facts	
Active Ingredient (in each softgel)	Purpose
Docusate Sodium 100 mg	Stool Softener
Uses	
•Relieves occasional constipation (irregularity) •Generally produces bowel movement in 12 to 72 hours	
Warnings	
Ask a doctor before use if you •have stomach pain, nausea or vomiting •have a sudden change in bowel habits that persists over a period of 2 weeks •are presently taking mineral oil. Stop use and ask a doctor if you need to use a laxative longer than 1 week •you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition. 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.	
Other Information	
• Each softgel contains: sodium 7 mg. Very low sodium • Store at 59°-77°F (15°-25°C) • Keep tightly closed • Tamper Evident. Do not use if imprinted seal under cap is missing or broken.	
Directions	
• Do not exceed recommended dose • Adults and children 12 years and older: take 1-3 softgels daily, usually 1 softgel daily after the first bowel movement, or as directed by a doctor. • Children under 12: ask a doctor	
Inactive Ingredients	
FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerol, PEG, sorbitol special, water.	

NDC 71335-9731-1

Docusate Sodium

100 mg

30 Capsules



Repackaged by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Major Pharmaceuticals



Package Insert

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-9731(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, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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:71335-9731-1	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2023	
2	NDC:71335-9731-2	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2023	
3	NDC:71335-9731-3	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/17/2023	
4	NDC:71335-9731-4	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
5	NDC:71335-9731-5	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/17/2023	
6	NDC:71335-9731-6	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
7	NDC:71335-9731-7	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
8	NDC:71335-9731-8	28 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
9	NDC:71335-9731-9	56 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
10	NDC:71335-9731-0	18 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/06/2024	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M007	11/15/2022	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9731) , RELABEL(71335-9731)

Revised: 9/2024

Bryant Ranch Prepack