

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

**GC 401(408)**

**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**

**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.

**Directions**

- adults and children 12 years and older: take 1-2 softgel daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

**Other information**

- **each softgel contains:** sodium 5 mg. very low sodium
- store at 15°C-25°C(59° F-77° F)

- keep tightly closed
- product from USA or Canada
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

**Inactive ingredients**

FD&C red #40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. Also contains D&C yellow #10 or FD&C yellow #6 (sunset yellow).

**HOW SUPPLIED**

Product: 71335-1539

NDC: 71335-1539-0 18 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-1 30 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-2 100 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-3 60 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-4 120 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-5 90 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-6 180 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-7 10 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-8 28 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-1539-9 56 CAPSULE, LIQUID FILLED in a BOTTLE

**Docusate Sodium 100mg Capsule**

<i>Packaged by Bryant Ranch</i>		<i>Barboursville, WV 26031</i>	
<b>Docusate Sodium 100mg Capsule</b>		LOT	RED OVAL 401
		142117	
Compare To: Colace 100mg Capsule Geri-Care Pharmaceutical Corp.		Keep all drugs out of reach of children.	
# 30	Exp: MM/YY	Store at room temp of 20°-25°C (68°-77°F)	
NDC	7133515391	013601142117	

<b>STOOL SOFTENER</b>
docusate sodium capsule, liquid filled
<b>Product Information</b>

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71335-1539(NDC:57896-408)
<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)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 3OWL53L36A)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	A92
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1539-2	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
2	NDC:71335-1539-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
3	NDC:71335-1539-0	18 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
4	NDC:71335-1539-8	28 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
5	NDC:71335-1539-6	180 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
6	NDC:71335-1539-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
7	NDC:71335-1539-9	56 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
8	NDC:71335-1539-4	120 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
9	NDC:71335-1539-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	
10	NDC:71335-1539-7	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part334	03/01/2018	

---

**Labeler** - Bryant Ranch Prepack (171714327)

**Establishment**

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1539) , RELABEL(71335-1539)

Revised: 5/2020

Bryant Ranch Prepack