

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

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**Drug Facts**

## **Active ingredient (in each softgel)**

Docusate sodium 250 mg

## **Purpose**

Stool softener laxative

## **Uses**

- for relief of occasional constipation
- this product generally produces a bowel movement within 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
- 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 signs of a serious condition.
- you need to use a 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.

## **Directions**

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

## Other information

- **each softgel contains:** sodium 15 mg
- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

## Inactive Ingredients

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan sorbitol

## Questions or comments?

Call **1-800-616-2471**

## HOW SUPPLIED

Docusate Sodium 250 mg

NDC: 71335-9738-1: 30 Capsules in a BOTTLE

NDC: 71335-9738-2: 60 Capsules in a BOTTLE

NDC: 71335-9738-3: 100 Capsules in a BOTTLE

NDC: 71335-9738-4: 7 Capsules in a BOTTLE

NDC: 71335-9738-5: 90 Capsules in a BOTTLE

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

## Docusate Sodium 250 mg Capsule



GTIN 00371335973810  
Lot 208620  
Exp 5/30/2026  
SN 0123456789

Each capsule contains: Docusate Sodium, 250 mg

Keep this and all drugs out of the reach of children.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see USP controlled Room Temperature).

Tamper Evident: Do not use if printed safety seal under cap is broken or missing.

**NDC 71335-9738-1**

**Docusate Sodium Capsules,  
USP**

**250 mg**

**30 Capsules**



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

Manufactured by:  
Major  
Pharmaceuticals



**STOOL SOFTENER**

docusate sodium capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71335-9738(NDC:0904-6999)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	P20
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71335-9738-1	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2023	
2	NDC:71335-9738-2	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/21/2023	
3	NDC:71335-9738-3	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/30/2024	
4	NDC:71335-9738-4	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2023	
5	NDC:71335-9738-5	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/30/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	09/30/2019	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9738) , RELABEL(71335-9738)

Revised: 5/2024

Bryant Ranch Prepack