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

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gc 401

#### 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

#### 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**

- 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

#### 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.

#### **Inactive ingredients**

FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerol, PEG, sorbitol special, water.

#### Questions or comments?

1-800-540-3765

#### **HOW SUPPLIED**

#### **Docusate Sodium 100 mg**

NDC: 72162-2255-1: 100 Capsules in a BOTTLE

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

Docusate Sodium 100mg Capsule #100

#### STOOL SOFTENER

docusate sodium capsule, liquid filled

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72162-2255(NDC:57896-401)

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ICATE CODUM (UNIL FOFOSTSIAO) (DOCUCATE LINIUMEDIZATORAC)	DOCUCATE CODULM	100

**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)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

MANNITOL (UNII: 30WL53L36A)

#### **Product Characteristics**

Color	red (reddish)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	<b>1</b> NDC:72162-2255-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/23/2024		

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/01/2000	

## Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2255) , RELABEL(72162-2255)

Revised: 2/2024 Bryant Ranch Prepack