STOOL SOFTENER EXTRA STRENGTH- 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.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 250 mg

Purpose

Stool softener laxative

Uses

- for the prevention of dry, hard stools
- 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 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 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 20-25ºC (68-77ºF); excursions permitted between 15-30ºC (59-86ºF)

Inactive ingredients

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

*may contain this ingredient

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

HOW SUPPLIED

Product: 71335-0632

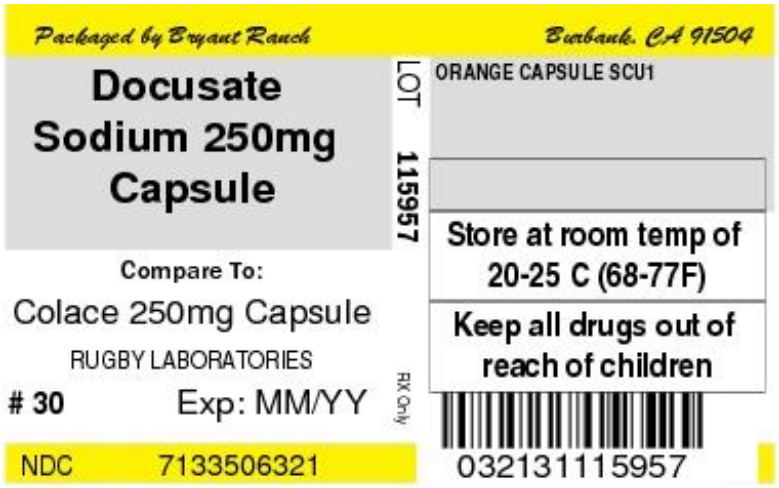
NDC: 71335-0632-1 30 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-0632-2 60 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-0632-3 100 CAPSULE, LIQUID FILLED in a BOTTLE

NDC: 71335-0632-4 7 CAPSULE, LIQUID FILLED in a BOTTLE

Docusate Sodium 250mg Capsule



STOOL SOFTENER EXTRA STRENGTH

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-0632(NDC:0536-1064)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	P20;SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0632-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
2	NDC:71335-0632-4	7 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
3	NDC:71335-0632-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
4	NDC:71335-0632-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/31/2015	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0632) , RELABEL(71335-0632)