# STOOL SOFTENER- docusate sodium capsule, liquid filled PuraCap Pharmaceutical LLC

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.

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#### STOOL SOFTENER

#### **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 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 at 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)

#### **Inactive ingredients**

anhydrous citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

#### Questions or comments?

Call toll free: 1-855-215-8180

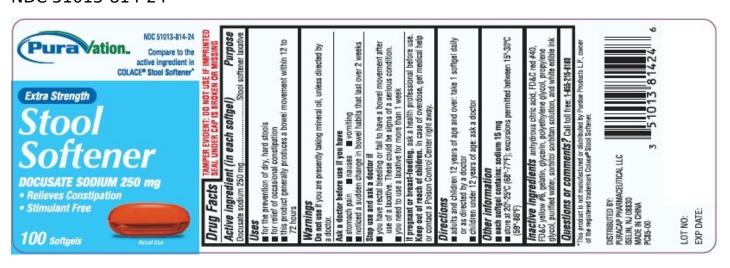
#### **Principal Display Panel**

STOOL SOFTENER

DOCUSATE SODIUM 250mg 100 SOFTGELS

Compare to the active ingredient in COLACE®

NDC 51013-814-24



# STOOL SOFTENER docusate sodium capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51013-814

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
L FOROSTSIAON (DOCUMENTE LINIU MARDS 710FAC)	DOCUEATE CODILINA	250

**DOCUSATE SODIUM** (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM 250 mg

# Inactive Ingredients

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Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	

# **Product Characteristics**

Color	red (clear)	Score	no score
Shape	capsule (oval)	Size	20mm
Flavor		Imprint Code	P4
Contains			

# Packaging

ı	- 0.0	9			
	# Item	Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:51	013-814-	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2021	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/07/2021	

# Labeler - PuraCap Pharmaceutical LLC (962106329)

# **Fstablishment**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Humanwell PuraCap Pharmaceutical (Wuhan) Co.,		<b>//21202207</b>	manufacture(51013-814), analysis(51013-	

Ltd. 421293201 814)

Revised: 5/2021

PuraCap Pharmaceutical LLC