DOCUSATE SODIUM- docusate sodium capsule
PD-Rx Pharmaceuticals, Inc.

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 100 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- results usually occurs 1 to 3 days after the first dose

Warnings

Do not use

Do not use if you are currently taking mineral oil, unless directed bya doctor

Ask a doctor before use if you

- stomach pain, nausea or vomiting
- have noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

you need to use a stool softner 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

- do not exceed recommended dose

adults and children over 12 years and older	take 1-3 softgels daily
children 2 to 12 years of age	take 1 softgel daily

children under 2 years	ask a doctor

Other information

- **Each capsule contains sodium 6mg**
- store at room temperature 15 º to 30 ºC (59 º to 86 ºF)
- protect from moisture

Inactive ingredients: FD&C Red #33,Edible Ink,FD&C Red #40,FD&C Yellow #6, Gelatin, Glycerin, Polyethylene Glycol, Purified Water, Sorbitol Special.

Questions?

Adverse drug event call: (866) 562-2756

HOW SUPPLIED

Supplied in bottles of 14, 30, 60, 90 and 180 softgels.

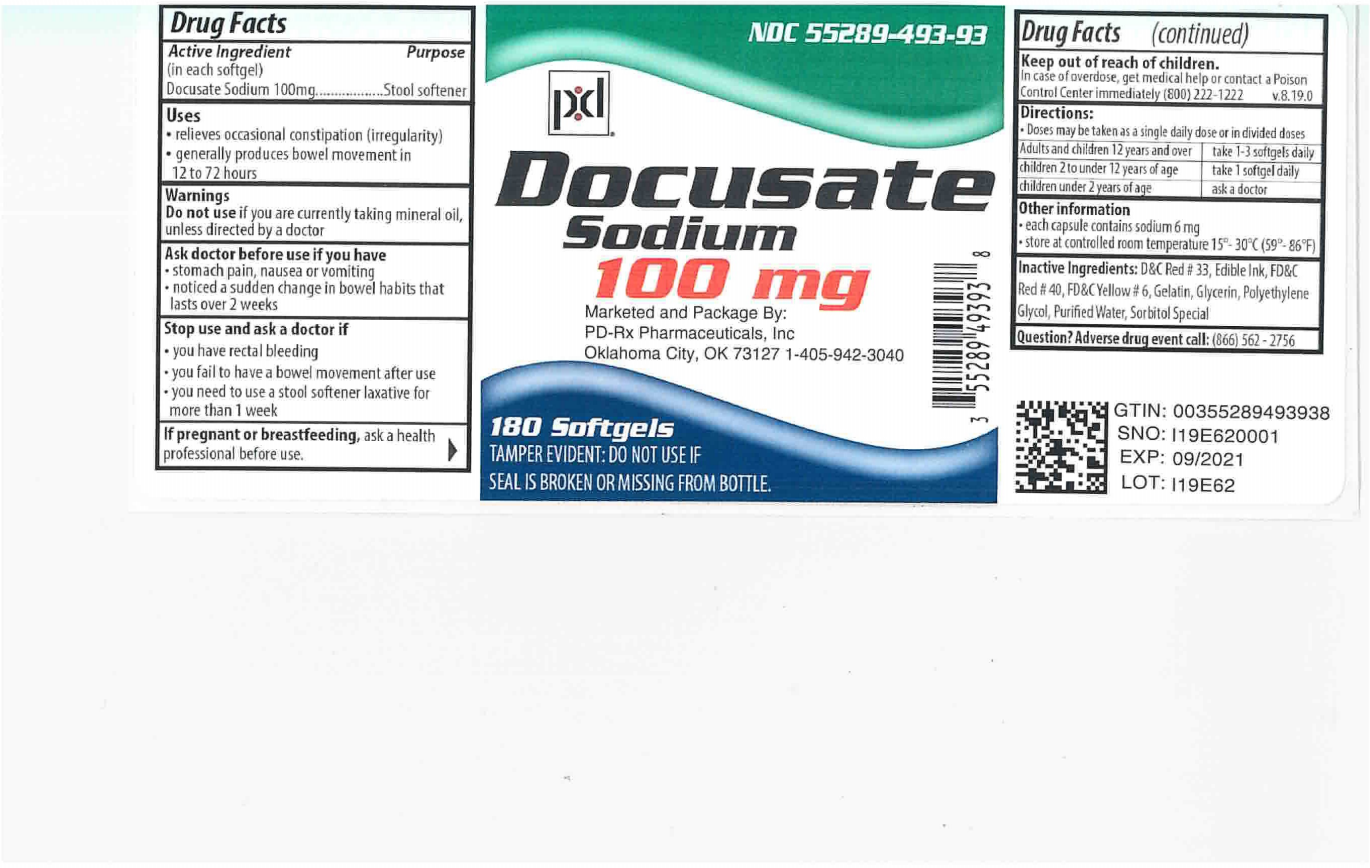
Principal Display Panel

*Compare to the active ingredient of Colace®

Docusate Sodium

Stool Softener

100 mg each



DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55289-493
Route of Administration	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**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red (Two-toned- white and clear red)	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	SC02
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55289-493-14	14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
2	NDC:55289-493-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
3	NDC:55289-493-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
4	NDC:55289-493-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
5	NDC:55289-493-93	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/12/2018	01/31/2038

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(55289-493)

Revised: 9/2019 PD-Rx Pharmaceuticals, Inc.