# STOOL SOFTENER- docusate sodium capsule, liquid filled Preferred 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.

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GC 401(408)

## Active ingredient (in each softgel)

Docusate Sodium 100 mg

#### **Purpose**

Stool Softener Laxative

#### 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**

- adults and children 12 years and older: take 1-2 softgel daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

#### Other information

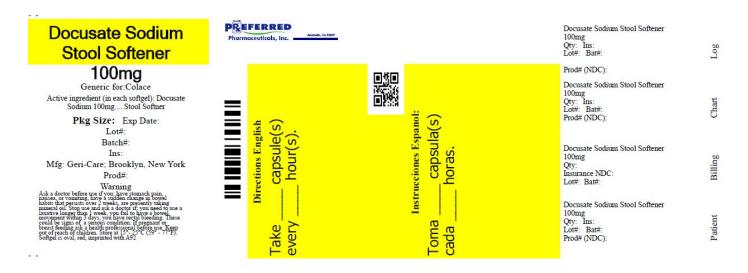
- each softgel contains: sodium 5 mg. very low sodium
- store at 15°C-25°C(59° F-77° F)

- keep tightly closed
- product from USA or Canada
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

## **Inactive ingredients**

FD&C red #40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. Also contains D&C yellow #10 or FD&C yellow #6 (sunset yellow).

### **Package Label**



#### STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7272(NDC:57896-408)		
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		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SORBITOL (UNII: 506T60A25R)			

WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics					
Color	red	Score	no score		
Shape	OVAL	Size	12mm		
Flavor		Imprint Code	A92		
Contains					

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:68788-7272-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/10 /20 19		
2	NDC:68788-7272-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/10/20 19		
3	NDC:68788-7272-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/10 /20 19		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	0 1/10/20 19		

## Labeler - Preferred Pharmaceuticals Inc. (791119022)

## **Registrant - Preferred Pharmaceuticals Inc.** (791119022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-7272)	

Revised: 5/2020 Preferred Pharmaceuticals Inc.