

**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)

<h1>Docusate Sodium Stool Softener</h1> <h2>100mg</h2> <p>Generic for: Colace</p> <p>Active ingredient (in each softgel): Docusate Sodium 100mg.....Stool Softner</p> <p><b>Pkg Size: Exp Date:</b></p> <p><b>Lot#:</b></p> <p><b>Batch#:</b></p> <p><b>Ins:</b></p> <p><b>Mfg: Geri-Care; Brooklyn, New York</b></p> <p><b>Prod#:</b></p> <p><b>Warning</b></p> <p>Ask a doctor before use if you have stomach pain, nausea, or vomiting, have a sudden change in bowel habits that persists over 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 fail to have a bowel movement within 3 days, you have rectal bleeding. 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. Store at 15° - 25°C (59° - 77°F). Softgels are oval, red, imprinted with A22.</p>	 <p><b>Pfizer</b> Pharmaceuticals, Inc.</p> <p>Ann Arbor, MI 48106</p>		<p><b>Directions English</b></p> <p>Take _____ capsule(s) every _____ hour(s).</p>	<p><b>Indicaciones Español:</b></p> <p>Toma _____ capsula(s) cada _____ horas.</p>	<p><b>Docusate Sodium Stool Softener</b> 100mg Qty: Ins: Lot#: Bat#:</p> <p><b>Prod# (NDC):</b></p> <p><b>Docusate Sodium Stool Softener</b> 100mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p><b>Docusate Sodium Stool Softener</b> 100mg Qty: Insurance NDC: Lot#: Bat#:</p> <p><b>Docusate Sodium Stool Softener</b> 100mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
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<b>WATER</b> (UNII: 059QF0KO0R)				
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)				
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)				
<b>MANNITOL</b> (UNII: 3OWL53L36A)				
<b>Product Characteristics</b>				
<b>Color</b>	red	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	12mm	
<b>Flavor</b>		<b>Imprint Code</b>	A92	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<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	01/10/2019	
2	NDC:68788-7272-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2019	
3	NDC:68788-7272-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2019	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part334	01/10/2019		

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

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

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