

**PREFERRED STOOL SOFTENER- docusate sodium capsule, liquid filled  
Reese Pharmaceutical Co**

*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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**Docusate Sodium 100 mg..... Stool Softener**

**Drug Facts**

**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool softener

**Uses**

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12 to 72 hours

**Warnings**

**Do not use**

- if you are presently taking mineral oil, unless told to do so by a doctor

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel movements 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 stool softener 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**

Take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

### Other information

- each softgel contains: sodium 7 mg
- store at room temperature 15° to 30°C (59° to 86°F)

### Inactive Ingredients

FD&C RED NO. 40, FD&C YELLOW NO. 6, GELATIN BOVINE, GLYCEROL, POLYETHYLENE GLYCOL, PURIFIED WATER, SORBITOL.

**Preferred Stool Softener**  
Docusate Sodium, 100 mg | Laxative  
100 SOFTGELS Actual Size

Compare to the active ingredient in Dulcolax® Liquid Gels\*

**Drug Facts**  
Active ingredient (in each softgel) Purpose  
Docusate Sodium 100 mg..... Stool Softener

**Uses** ■ relieves occasional constipation ■ generally produces bowel movement within 12 to 72 hours

**Warnings**  
**Ask a doctor before use if you have** ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over a period of 2 weeks  
**Ask a doctor before use if** ■ you are presently taking mineral oil

**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 breastfeeding**, ask a health professional before use.  
**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Distributed By: **Reese Pharmaceutical**  
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MADE IN ROMANIA  
REV. 5/23 DS01100R  
\*This product is not manufactured or distributed by Sanofi-Aventis, owner of the registered trademark Dulcolax®.

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## PREFERRED STOOL SOFTENER

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10956-621
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OVAL)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	SCU1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-621-00	1 in 1 CARTON	05/11/2023	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/11/2023	

**Labeler** - Reese Pharmaceutical Co (004172052)

**Registrant** - Reese Pharmaceutical Co (004172052)

Revised: 5/2023

Reese Pharmaceutical Co