

**DOCUSATE SODIUM - STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled**

**Cardinal Health 107, LLC**

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**Docusate Sodium - Stool Softener Laxative**

***Drug Facts***

***Active ingredient (in each softgel)***

Docusate Sodium 100 mg

***Purpose***

Stool softener laxative

***Uses***

- for relief of occasional constipation (irregularity)
- This generally produces a bowel movement within 12 to 72 hours.

***Warnings***

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

- abdominal pain, nausea, or vomiting
- a sudden change in bowel habits that lasts over 14 days

**Ask a doctor or pharmacist before use if you are** presently taking mineral oil

**Stop use and ask a doctor if**

- you have rectal bleeding or no bowel movement after using this product.

These can 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 care professional before use.

This unit dose package is not child resistant and is Intended for Institutional Use Only.

**Keep out of reach of children**

**Overdose Warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

***Directions***

- take softgel with a full glass (8 oz) of water
-

adults and children 12 years of age and older	take 1 to 3 softgels daily or as directed by a doctor. This dose may be taken as a single daily dose or in divided doses.
children 6 to under 12 years of age	take 1 softgel daily or as directed by a doctor
children under 6 years of age	ask a doctor

### ***Other information***

- **each softgel contains:** sodium 10 mg (very low sodium)
- store at 25°C (77°F) in a dry place. Avoid excessive heat 40°C (140°F).

### ***Inactive ingredients***

edible white ink, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, isopropyl alcohol, light mineral oil, medium chain triglycerides, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution

### ***Questions or comments?***

**(800)616-2471**

Distributed by:

**MAJOR® PHARMACEUTICALS**

Livonia, MI 48152

**Distributed By:**

**Cardinal Health**

Dublin, OH 43017

L57466800124

Product of UAE

Packaged and Quality Assured in the USA

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**


**READ FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

### **Principal Display Panel**

Docusate Sodium

100 mg

10 Softgels



**R122**

**NDC 55154-3369-0**

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**Stool Softener Laxative**

**10 SOFTGELS**

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Avoid excessive heat 40° C (140° F).

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Ask a doctor before use if you have -abdominal pain, nausea or vomiting  
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Ask a doctor or pharmacist before use if you are presently taking mineral oil  
Stop use and ask a doctor if -you have rectal bleeding or no bowel movement after using this product .These can be signs of a serious condition.  
-you need to use a laxative for more than 1 week  
**WARNING:** This Unit Dose package is not child resistant and is Intended for Institutional Use Only. If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children.  
**Overdose Warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

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Distributed by MAJOR® PHARMACEUTICALS  
Indianapolis, IN 46268  
Product of UAE  
Packaged and Quality Assured in the USA  
Distributed by Cardinal Health  
Dublin, OH 43017  
L57466800124  
Lot:            Exp:

## DOCUSATE SODIUM - STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55154-3369(NDC:0904-7183)	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	100 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				
<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>	777	
<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:55154-3369-0	10 in 1 BAG	09/04/2021	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<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 Drug	M007	09/04/2021		

**Labeler** - Cardinal Health 107, LLC (118546603)

