

## **DOCUSATE SODIUM- docusate sodium capsule**

### **Major Pharmaceuticals**

-----

#### **Drug Facts**

##### **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**

##### **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 habits that last 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 a signs of a serious condition.
- you need to use a 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 (1-800-222-1222) 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 5 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

### Inactive ingredients

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitan, sorbitol

### Questions or comments?

Call **1-800-616-2471**

### Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener†

Docusate sodium 100 mg

Stool Softener Laxative

Softgels

†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

Distributed by:

**MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

### Product Label

MAJOR

NDC 0904-6998-80  
Compare to the active  
ingredient in Colace® Regular  
Strength Stool Softener

# Docusate Sodium

100 mg

Stool Softener  
Laxative

1000 Softgels



TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts	
<b>Active ingredient (in each softgel)</b> Docusate sodium 100 mg	<b>Purpose</b> Stool softener laxative
<b>Uses</b> ■ relieves occasional constipation (irregularity) ■ generally produces bowel movement in 12 to 72 hours	
<b>Warnings</b> Do not use if you are presently taking mineral oil, unless told to do so by a doctor. <b>Ask a doctor before use if you have:</b> ■ stomach pain ■ nausea or vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks <b>Stop use and ask a doctor if:</b> ■ 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 <b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b> ■ 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 1-3 softgels daily children 2 to under 12 years of age take 1 softgel daily children under 2 years ask a doctor	
<b>Other information</b> ■ each softgel contains: sodium 5 mg ■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)	
<b>Inactive ingredients</b> edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol	
<b>Questions or comments?</b> Call 1-800-616-2471	

\*This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

PLD-F570A LB007603  
Rev. 05/20 M-58 Re-order No. 70189



Distributed by:  
MAJOR PHARMACEUTICALS  
17777 N Laurel Park Drive, Suite 233  
Livonia, MI 48152

Exp. Date:

Lot No.:

## MAJOR PHARMACEUTICALS Stool Softener Laxative

### DOCUSATE SODIUM

docusate sodium capsule

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6998
<b>Route of Administration</b>	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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O921CV9RU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

#### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
--------------	--------	--------------	----------

Shape		OVAL	Size		12mm
Flavor			Imprint Code		P51
Contains					
Packaging					
#	Item Code	Package Description		Marketing Start Date	Marketing End Date
1	NDC:0904-6998-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		02/28/2020	10/28/2025
2	NDC:0904-6998-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		02/28/2020	10/28/2025
Marketing Information					
Marketing Category		Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug		M007		02/28/2020	10/28/2025

**Labeler** - Major Pharmaceuticals (191427277)