

# **STOOL SOFTENER- docusate sodium capsule, liquid filled**

## **Major Pharmaceuticals**

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### **Drug Facts**

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

Docusate sodium 250 mg

#### **Purpose**

Stool softener laxative

#### **Uses**

- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

#### **Warnings**

##### **Do not use**

if you are presently taking mineral oil, unless directed 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 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 right away.

#### **Directions**

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

**Other information**

- **each softgel contains:** sodium 15 mg
- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

**Inactive Ingredients**

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan sorbitol

**Questions or comments?**

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

**Principal Display Panel****Extra Strength****Docusate Sodium****250 mg****Stool Softener****Laxative**

Softgels

**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 0904-6999-80

# Extra Strength Docusate Sodium

250 mg

Stool Softener  
Laxative

1000 Softgels

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

<b>Drug Facts</b>	<b>Purpose</b> Stool softener laxative
<b>Active ingredient (in each softgel)</b> Docusate sodium 250 mg	
<b>Uses</b> <ul style="list-style-type: none"> <li>for relief of occasional constipation</li> <li>this product generally produces a bowel movement within 12 to 72 hours</li> </ul>	
<b>Warnings</b> <ul style="list-style-type: none"> <li>Do not use if you are presently taking mineral oil, unless directed by a doctor.</li> <li>Ask a doctor before use if you have <ul style="list-style-type: none"> <li>stomach pain</li> <li>nausea</li> <li>vomiting</li> </ul> </li> <li>noticed a sudden change in bowel habits that lasts over 2 weeks</li> </ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.</li> <li>you need to use a laxative for more than 1 week</li> </ul>	
<b>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.</b>	
<b>Directions</b> <ul style="list-style-type: none"> <li>adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor</li> <li>children under 12 years of age: ask a doctor</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>each softgel contains: sodium 15 mg</li> <li>store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)</li> </ul>	
<b>Inactive ingredients</b> edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol	
<b>Questions or comments?</b> Call 1-800-616-2471	

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MAJOR® PHARMACEUTICALS  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152

Rev. 10/19 M-58 Re-order No. 70193



Exp. Date:  
Lot No.:

PLD-A610A  
L8006445

## MAJOR Extra Strength Docusate Sodium 250 mg

### STOOL SOFTENER

docusate sodium capsule, liquid filled

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6999
<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	250 mg

#### Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 3OWL53L36A)	
SORBITAN (UNII: 6O92ICV9RU)	

#### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
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<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	P20
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6999-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	
2	NDC:0904-6999-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	09/30/2019	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 4/2024

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