

# **STOOL SOFTENER LAXATIVE- 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**

- relieves occasional constipation (irregularity)
- 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 (1-800-222-1222) 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 13 mg
- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

### **Inactive Ingredients**

anhydrous citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mannitol, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, white ink

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

#### **Extra Strength**

#### **Docusate Sodium**

docusate sodium 250 mg

Stool Softener Laxative

- stimulant-free
- relief of occasional constipation

Softgels

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

Distributed by:

#### **MAJOR PHARMACEUTICALS**

Indianapolis, IN 46268

### **Product Label**


**MAJOR<sup>®</sup>** NDC 0904-7281-60

**extra strength docusate sodium**

**docusate sodium 250 mg**  
stool softener laxative

- stimulant-free
- relief of occasional constipation


**100 softgels** actual size



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

<b>Drug Facts</b>	<p><b>Active ingredient (in each softgel)</b> Docusate sodium 250 mg</p> <p><b>Uses</b> ■ relieves occasional constipation (irregularity) ■ this product generally produces a bowel movement within 12 to 72 hours</p> <p><b>Warnings</b> Do not use if you are presently taking mineral oil, unless directed by a doctor. <b>Ask a doctor before use if you have</b> ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks</p> <p><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 laxative for more than 1 week</p> <p><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.</p> <p><b>Directions</b> ■ 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</p> <p><b>Other information</b> ■ each softgel contains: sodium 13 mg ■ store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)</p> <p><b>Inactive ingredients</b> anhydrous citric acid, FD&amp;C red #40, FD&amp;C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, white ink</p> <p><b>Questions or comments?</b> Call 1-877-753-9835 Monday-Friday 9AM-5PM EST</p>
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Distributed by:  
**MAJOR<sup>®</sup> PHARMACEUTICALS**  
Indianapolis, IN 46266  
**(800) 616-2471**  
www.major-rugby.com  
Product of China  
Rev. 12/24  
M-58  
Re-order No. 701324  
PLD-E727A Lot No.:  
LB009995

  
**0904728160** 2  
 3  
 Exp. Date:

## MAJOR Stool Softener Laxative

### STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7281
<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	250 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>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>SORBITAN</b> (UNII: 6O921CV9RU)	

#### Product Characteristics

<b>Color</b>	orange (Clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	P4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7281-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2022	
2	NDC:0904-7281-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	10/14/2022	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 12/2024

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