

**STOOL SOFTENER- docusate sodium capsule  
NORTHEAST PHARMA (Heartland Pharma)**

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**Drug Facts**

**Active Ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool softener laxative

**Purpose**

Stool Softener Laxative

**Uses**

- relieves occasional constipation and irregularity
- generally produces a bowel movement in 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
- a sudden change in bowel habits that lasts more than 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding or no bowel movement after using 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 care 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 1-3 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°); 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 1-800-383-0648

## Principal Display Panel

Compare to active ingredient in COLACE® REGULAR STRENGTH†

## STOOL SOFTENER

Docusate Sodium 100 mg

Stool Softener Laxative

- Gentle
- dependable
- Stimulant-Free

Softgels

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

Distributed by NORTHEAST PHARMA

South Burlington, VT 05403

[www.heartlandpharma.com](http://www.heartlandpharma.com)

## Product Label

NDC 80136-951-80



# STOOL SOFTENER

Docusate Sodium, 100 mg  
Stool Softener Laxative

- ✓ Gentle ✓ Dependable
- ✓ Stimulant-Free

Compare to active ingredient in COLACE®  
**REGULAR STRENGTH STOOL SOFTENER†**



Actual Size

**100 Softgels**

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

<b>Drug Facts</b>	
<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 ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 2 weeks	

**Drug Facts (continued under label)**

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

Distributed by: **NORTHEAST PHARMA**  
South Burlington, VT 05403  
www.heartlandpharmaco.com

Rev. 05/21  
Re-order No.  
85180



8 50021 28518 0  
Lot No.:  
PLD-A670A  
LB008522

Exp. Date:



<b>Drug Facts (continued)</b>	
<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, ask a health professional before use.</b> <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.	
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<b>Questions or comments?</b> Call 1-800-383-0648	

**HEARTLAND PHARMA Stool Softener**

**STOOL SOFTENER**

docusate sodium capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80136-951
<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)	

<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	P51
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-951-80	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2021	06/28/2025

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	06/28/2021	06/28/2025

**Labeler** - NORTHEAST PHARMA (Heartland Pharma) (081232935)

Revised: 4/2024

NORTHEAST PHARMA (Heartland Pharma)