

**DOCUSATE SODIUM- docusate sodium 100mg capsule**  
**Pharbest Pharmaceuticals, Inc.**

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**Docusate Sodium 100 mg Softgels**

**Drug Facts**

**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool softener

**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 lasts over 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have 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

**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. (1-800-222-1222)

**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 6 mg**
- **VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

keep tightly closed.

### **Inactive ingredients**

D&C Red #33, edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, titanium dioxide

### **Questions or comments?**

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

**PHARBEST**

**NDC 16103-0399-11**

**\*Compare to the active ingredient of Colace®**

**Docusate**

**Sodium**

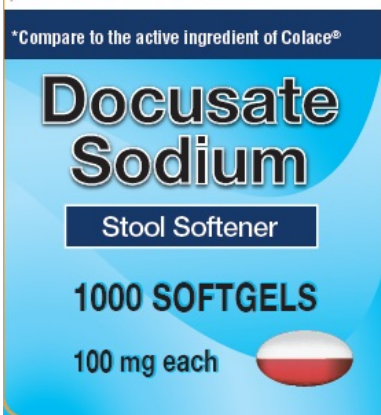
**Stool Softener**

**1000 SOFTGELS**

**100 mg each**

**THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN**

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



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 These could be signs of a serious condition.  
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Manufactured by:  
 Pharbest Pharmaceuticals, Inc.  
 Farmingdale, NY 11735

\*This product is not manufactured or distributed by Amio Health L.P., owner of the registered trademark Colace®.

# DOCUSATE SODIUM

docusate sodium 100mg capsule

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16103-399
<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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C Red No. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
<b>Color</b>	red (Two-toned- white and clear red)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	SCU2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-399-08	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	
2	NDC:16103-399-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	03/01/2016	

**Labeler** - Pharbest Pharmaceuticals, Inc. (557054835)

**Registrant** - Pharbest Pharmaceuticals, Inc (557054835)

## Establishment

Name	Address	ID/FEI	Business Operations
SWSSCAPS Romania srl		565466997	manufacture(16103-399)

Revised: 1/2024

Pharbest Pharmaceuticals, Inc.