

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled**  
**Softgel Healthcare Pvt Ltd**

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**Docusate Sodium Capsules USP 100 mg**

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

Docusate Sodium USP 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 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 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.

***Directions***

Take only by mouth. Doses may be taken as a single daily dose or in divided doses.

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adults and children 12 years and over	take 1-3 capsules daily
children 2 to under 12 years of age	take 1 capsule daily
children under 2 years	ask a doctor

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***Other information***

- **each softgel contains:** Sodium 5 mg
- store at 25°C (77°F); excursion permitted between 15°-30°C (59°-86°F).

Keep tightly closed.

***Inactive ingredient***

FD&C red no.40, FD&C yellow no.6, gelatin, glycerin, polyethylene glycol 400, propylene glycol, sorbitol sorbitan solution, water.

**TAMPER EVIDENT**

Do not use if safety seal under cap is broken or missing

**Manufactured by**

**Softgel Healthcare Pvt. Ltd.,**

Survey No. 20/1,

Vandalur-Kelambakkam Road,

Pudupakkam Village,

Kancheepuram District,

Tamilnadu - 603 103, India.

Mfg. Lic. No.: XXXXXXXXXXXXX

**PRINCIPAL DISPLAY PANEL**

FRONT PAGE  
Multilayer Roll Direction



30 mm

NDC 35916-0440-1

**Docusate Sodium Capsules USP 100 mg**

30 Softgels

**REGULAR STRENGTH**

**Stool Softener**

- Gentle, Effective Relief
- Cramp & Stimulant - free

\*Compared to the active ingredient of Colace\*

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

**Drug Facts**

**Active Ingredient (In each softgel)**  
Docusate sodium USP 100 mg-----Stool softener

**Uses**

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- generally produces bowel movement in 12 to 72 hours

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**Ask a doctor before use: If you have**

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Manufactured by:  
**Softgel Healthcare Pvt. Ltd.,**  
Survey No. 20/1,  
Vandatur-Kelambakkam Road,  
Pudupakkam Village,  
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Tamilnadu - 603 103, India.

Mfg. Lic. No.: xxxxxxxxxxxxxx

unvarnished Area  
for 2D Barcode &  
Batch Details  
LH - 25 x 20 mm

100 mm

Back

30 mm

8 mm  
Blank  
for  
Glue  
Area

**Drug facts (continued)**

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\*This product is not manufactured or distributed by Atlantis Consumer Healthcare Inc. owner of the registered trademark Colace®

8 mm  
Blank  
for  
Glue  
Area

100 mm

## DOCUSATE SODIUM

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0440
<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

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Product Characteristics

<b>Color</b>	red (Transparent)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0440-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	08/31/2024	

**Labeler** - Softgel Healthcare Pvt Ltd (675584180)

Revised: 8/2024

Softgel Healthcare Pvt Ltd