

# **STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Proficient Rx LP**

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**DRUG FACTS**

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

Docusate Sodium 100 mg

## **Purpose**

Stool softener laxative

## **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**

- 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 a bowel movement after using a laxative. These could be a sign 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 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 7 mg
- store at 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

### Inactive ingredients

citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitol special, white edible ink

### Questions or comments?

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

### Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener†

DOCUSATE SODIUM, 100 mg

STOOL SOFTENER LAXATIVE

Gentle, Dependable

Stimulant-free

SOFTGELS

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

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

**DISTRIBUTED BY:**

**MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268

**(800) 616-2471**

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

**RELABELED BY:**

**Proficient Rx LP**

Thousand Oaks, CA 91320

## Product Label




Scan Here



NDC 82804-097-00

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320



3  
8280409700  
5

# Docosate Sodium 100mg

## #100 Softgels

Each softgel contains: Docosate sodium 100 mg  
Stool softener laxative

*Red, unscored, oval and capsule shaped softgels with imprint code PC1*

Product ID: XD009700

Dist. By: MAJOR® PHARMACEUTICALS, Indianapolis, IN 46268

Store at 25°C (77°F)

Keep medication out of the reach of children

### Stool Softener Laxative



GTIN: 00382804097005  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000

Docosate Sodium 100mg  
#100 Softgels  
Lot #:00000 SN# MASTER  
NDC 82804-097-00 Exp:00/00/00

Docosate Sodium 100mg  
#100 Softgels  
Lot #:00000 SN# MASTER  
NDC 82804-097-00 Exp:00/00/00

Docosate Sodium 100mg  
#100 Softgels  
Lot #:00000 SN# MASTER  
NDC 82804-097-00 Exp:00/00/00

## STOOL SOFTENER LAXATIVE

docosate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82804-097(NDC:0904-7280)
<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	100 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, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

**GLYCERIN** (UNII: PDC6A3C0OX)

**CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP)

**SORBITAN** (UNII: 6O92ICV9RU)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Oval)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	PC1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82804-097-00	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	11/15/2022	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(82804-097) , RELABEL(82804-097)

Revised: 4/2024

Proficient Rx LP