

STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled

Major Pharmaceuticals

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

MAJOR® NDC 0904-7280-60
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ingredient in Colace® Regular
Strength Stool Softener†

Docusate Sodium

100 mg

**Stool Softener
Laxative**

Gentle,
Dependable
Stimulant-Free

100 Softgels

Actual Size

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Drug Facts (continued under label)

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Distributed by:

MAJOR® PHARMACEUTICALS, Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com

Rev. 11/22 M-58 Re-order No. 701322

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LB009049

Lot No.: Exp. Date:

**PEEL
HERE**

Drug Facts (continued)

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MAJOR Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7280(NDC:53345-008)
Route of Administration	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)				
GELATIN (UNII: 2G86QN327L)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
SORBITAN (UNII: 6O92ICV9RU)				
Product Characteristics				
Color	red		Score	no score
Shape	CAPSULE (Oval)		Size	13mm
Flavor			Imprint Code	PC1
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7280-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2022	
2	NDC:0904-7280-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007		11/15/2022	

Labeler - Major Pharmaceuticals (191427277)