# BASIC CARE STOOL SOFTENER- docusate sodium capsule, liquid filled Amazon.com Services LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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## **Amazon Stool Softener 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 you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

## Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

#### 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 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 20-25°C (68-77°F)

# **Inactive ingredients**

D&C red no. 33, edible ink, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

# Questions?

1-800-719-9260

# **Principal Display Panel**

Softgels

Compare to Colace® active ingredient

Stool Softener

Docusate Sodium 100 mg

Stool Softener

actual size

Laxative

Gentle

Dependable Effect

Stimulant-Free

100 SOFTGELS



Drug Facts (continued)

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adults and children lake 1 - 3
12 years and over softgels daily children 2 to under take 1
12 years of age softgel daily children under ask a doctor 2 years.

## **BASIC CARE STOOL SOFTENER**

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-486
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	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6O92ICV9RU)		

# TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics			
Color	RED, WHITE (to off beige)	Score	no score
Shape	OVAL (softgel)	Size	13mm
Flavor		Imprint Code	L486
Contains			

Packaging				
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:72288-486-78	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/14/2020	

# Labeler - Amazon.com Services LLC (128990418)

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