

**DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Marlex Pharmaceuticals Inc**

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.

Docusate Sodium

DOCUSATE SODIUM- docusate sodium capsule Marlex Pharmaceuticals, Inc.

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Docusate Sodium 100 mg

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 directed 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.
- you need to use stool softener laxative for more than 1 week

These could be signs of a serious condition.

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

adults and children 12 years and over	take 1 - 3 softgels once daily or in divided doses
children 2 to under 12 years of age	1 softgel once daily
children under 2 years	ask a doctor

Other information

- each softgel contains: sodium 7 mg
- store at room temperature 15°-25°C (59°-77°F) and avoid excessive heat

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400 NF, purified water, sorbitol

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

*Marlex Pharmaceuticals, Inc., is not affiliated with the owner of the trademark Colace®

Distributed by:

**Marlex Pharmaceuticals, Inc.
New Castle, DE 19720**

Made in Romania

PRINCIPAL DISPLAY PANEL

**NDC 10135-0111-01
Docusate Sodium
100 mg
100 Softgels**

Distributed by: Marlex Pharmaceuticals, Inc.
 New Castle, DE 19720, Made in USA.
 Website: <http://www.marlexpharm.com>

NDC 10135-0111-01

Docosate Sodium

100 mg

**Stool Softener Laxative
 Relief of Constipation**

DO NOT USE IF IMPRINTED SAFETY SEAL
 UNDER CAP IS BROKEN OR MISSING.

100 Softgels
 Stimulant Free



N 3 10135 11101 5



Drug Facts
Active Ingredient (in each softgel) Purpose Docosate sodium 100 mg ...stool softener laxative
Uses <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces bowel movement in 12 to 72 hours
Warnings Do not use <ul style="list-style-type: none"> If you are presently taking mineral oil, unless told to do so by a doctor
Ask a doctor before use if you have <ul style="list-style-type: none"> 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. When using this product do not exceed the maximum recommended daily dosage in a 24-hour period

REV. 1 4/17 SC
Drug Facts (continued on back)
 Peel Here For More Drug Facts

Drug Facts (continued)	
Stop use and ask a doctor if <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Take only by mouth. Dose 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 <ul style="list-style-type: none"> each softgel contains NMT: <ul style="list-style-type: none"> sodium 7 mg magnesium 1 mg potassium 1 mg calcium 1 mg store at 20-25°C (68-77°F) 	
Inactive Ingredients glycol, glycerin, purified water, gelatin, sorbitol, FD&C Red #40, FD&C yellow #6	

DOCUSATE SODIUM			
docosate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-111
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)		
	GLYCERIN (UNII: PDC6A3C0OX)		

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-111-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/01/2017	

Labeler - Marlex Pharmaceuticals Inc (782540215)

Revised: 10/2021

Marlex Pharmaceuticals Inc