DOCUSATE SODIUM- docusate sodium capsule, liquid filled
Redpharm Drug, 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.

Perrigo 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 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.

When using this product

do not exceed the maximum recommended daily dosage in a 24-hour period

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, purified water, sorbitol sorbitan solution, titanium dioxide

Questions?

1-800-719-9260

Principal Display Panel

Compare to Colace ® active ingredient

Docusate Sodium

100 mg

Stool Softener Laxative

Gentle and Predictable

Relief of Constipation

100 Softgels

Stimulant Free

Compare to Colace®
active ingredient

Perrigo®

NDC 45802-**486**-78

Docusate Sodium

100 mg

Stool Softener Laxative

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Relief of Constipation

100 Softgels Stimulant Free

Drug Facts (continued)

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Questions? 1-800-719-9260

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Distributed By Perrigo
Allegan, MI 49010 • www.perrigo.com

: 48678 RT F3

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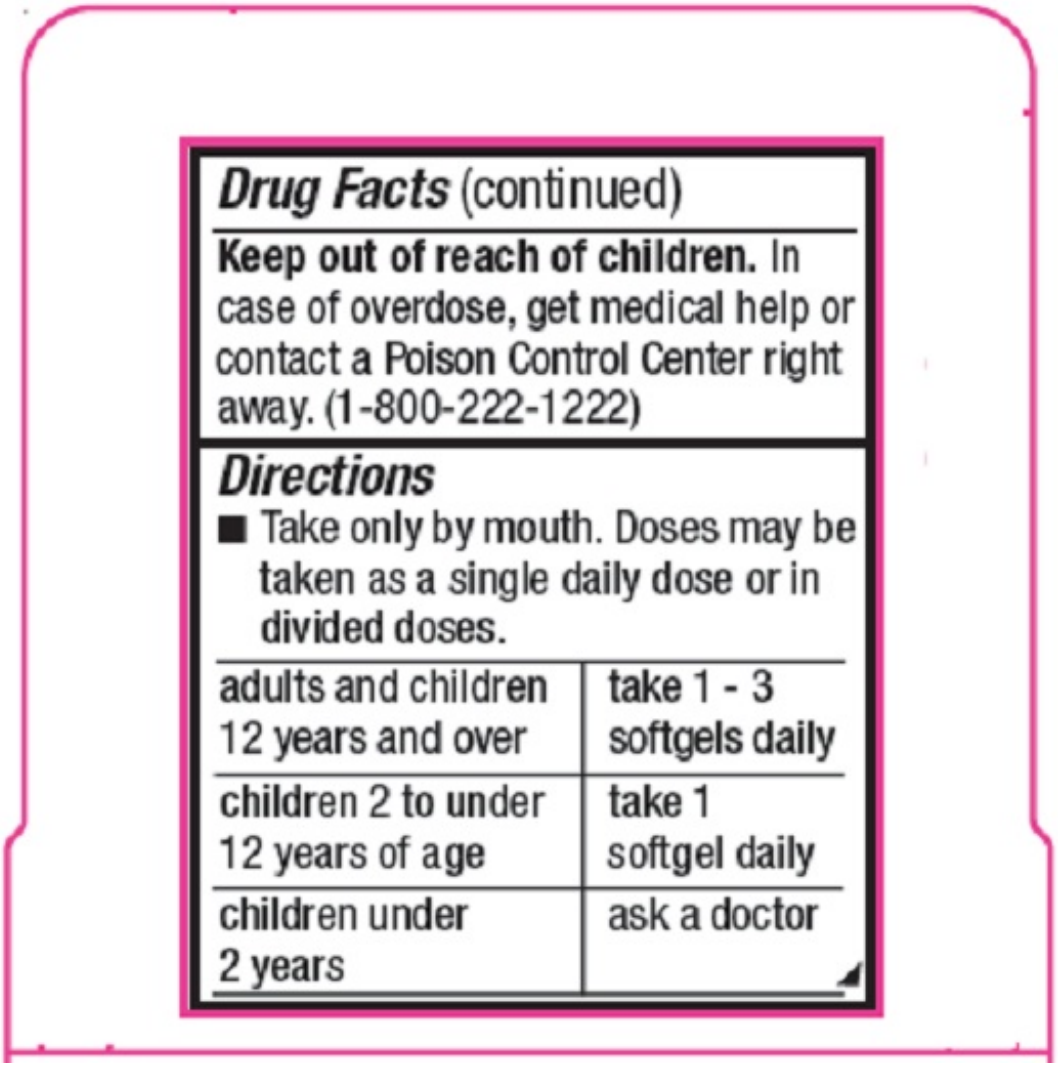

Drug Facts (continued)

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DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67296-1835(NDC:45802-486)
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: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red, white (to off beige)	**Score**	no score
Shape	OVAL (softgel)	**Size**	13mm
Flavor		**Imprint Code**	L486
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1835-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2008	
2	NDC:67296-1835-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/28/2008	

Labeler - Redpharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
Redpharm Drug, Inc.		828374897	repack(67296-1835)