# DOCUSATE SODIUM- docusate sodium capsule, liquid filled Padagis Israel Pharmaceuticals Ltd

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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#### 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

Compare to Colace® active ingredient

# Perrigo<sub>®</sub>

NDC 45802-486-78

# Docusate Sodium

**Stool Softener Laxative** 

Gentle and Predictable Relief of Constipation

100 Softgels

Stimulant Free

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Questions? 1-800-719-9260

Drug Facts (continued) Other information

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glycerin, polyethylene glycol, purified edible ink, FD&C blue no. 1, FD&C red no. 40, FD&C yellow no. 6, gelatin *Inactive ingredients* D&C red no. 33,

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

Distributed By Perrigo Allegan, MI 49010 • www.perrigo.com 48678 RT F

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#### **DOCUSATE SODIUM**

docusate sodium capsule, liquid filled

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45802-486

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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: 3WJQ0SDW1A)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
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			

Ш	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:45802-486-	100 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 - Padagis Israel Pharmaceuticals Ltd (600093611)

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