

DOCUSATE SODIUM- docusate sodium capsule, gelatin coated

Marc Glassman, 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

Active ingredient

Docusate sodium 100mg

Purpose

Stool softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation

This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for longer than 1 week unless directed by a doctor

Ask a doctor before use if you

notice a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if you

- have rectal bleeding
- fail to have a bowel movement occur after use

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Adults and children 12 years and over: take 1 to 3 capsules, preferably at bedtime
- Children 2 to under 12 years of age: take 1 capsule at bedtime

- Children under 2 years of age: ask a doctor

Other information

each capsule contains: sodium 5mg

store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

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

Principal Display Panel


NDC 68998-314-01 * Compare to the active ingredient in Colace[®] Stool Softener

Marc's

Docusate Sodium

STOOL SOFTENER

Gentle
Stimulant Free
Effective



100 Capsules

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

Drug Facts

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Continued On Back Of Label

* This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace[®].

Distributed By:
Marc Glassman, Inc.
West 130th Street
Cleveland, OH 44130

LB1249
R1115

Lot: _____
Exp: _____
PEEL HERE 



Drug Facts (continued)

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Docusate Sodium

DOCUSATE SODIUM

docusate sodium capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-314
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg
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Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-314-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/23/2014	

Labeler - Marc Glassman, Inc. (094487477)

Revised: 12/2016

Marc Glassman, Inc.