

**STOOL SOFTENER- docusate sodium capsule, liquid filled
Preferred Pharmaceuticals Inc.**

gc 401

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

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you need to use a laxative longer than 1 week
- you have rectal bleeding or fail to have a bowel movement. 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

- do not exceed recommended dose
- adults and children 12 years and older: take 1-3 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by a doctor
- children under 12: consult a doctor

Other information

- **each softgel contains:** sodium 7 mg. Very low sodium
- store at 59°-77°F (15°-25°C)
- keep tightly closed
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

Repackaged By: Preferred Pharmaceuticals Inc.

Inactive ingredients

FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerin, PEG, sorbitol special, water.

Package Label

Docusate Sodium 100mg
Generic for Colace

Active ingredient (in each softgel): Docusate Sodium 100mg...Stool Softner

Pkg Size: Exp Date:
Lot#: Batch#: Ins:
Mfg: Geri-Care, Brooklyn, New York
Prod#:

Warning
Ask a doctor before use if you have stomach pain, nausea, or vomiting, have a sudden change in bowel habits that persists over 2 weeks, are presently taking mineral oil. Stop use and ask a doctor if you need to use a laxative longer than 1 week, you fail to have a bowel movement within 3 days, you have rectal bleeding. 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. Store at 59°-77°F (15°-25°C). Softgel is oval, red, imprinted with SCU1.

Directions English
Take ___ capsule(s) every ___ hour(s).

Instrucciones Espanol:
Toma ___ capsula(s) cada ___ horas.

CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Docusate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Docusate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Docusate Sodium 100mg
Qty: Ins:
Insurance NDC:
Lot#: Bat#:

Docusate Sodium 100mg
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Log
Chart
Billing
Patient

STOOL SOFTENER			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8919(NDC:57896-401)
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)			

GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KOOR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	red (reddish)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8919-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2015	
2	NDC:68788-8919-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2015	
3	NDC:68788-8919-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	334	09/18/2015	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8919)