

STOOL SOFTENER- docusate sodium capsule, liquid filled
Cardinal Health

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.

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

- adults and children 12 years and older: take 1-2 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

Other information

- **each softgel contains:** sodium 5 mg. very low sodium
- store at 15°C-25°C(59° F-77° F)
- keep tightly closed

- product from USA or Canada
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

Inactive ingredients

FD and C red #40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. May also contain D and C yellow #10, FD and C yellow #6 (sunset yellow), mannitol.

Compare to active ingredient in Colace^{R*}

*This product is not manufactured or distributed by the owner of the registered trademark Colace^R.

DIST. BY: GERI-CARE PHARMACUETICALS CORP.

1650 63rd Street, Brooklyn, NY 11204

REV 0112

Cardinal Health

Zanesville, OH 43701

IT48469450613

Principal Display Panel

Stool Softener

Docusate Sodium

100 mg Softgels

**STOOL SOFTENER
DOCUSATE SODIUM
100 mg softgels**

LOT: xxxxxxxxxx EXP: xx/xx/xx

LTC48469450314



CUSTOMER ID

Principal Display Panel

Stool Softener

Docusate Sodium

100 mg softgels

QTY 28

NDC 55154-1876-3 (CARDINAL HEALTH)
STOOL SOFTENER
DOCUSATE SODIUM 100 mg softgels
QTY 28



Active ingredient (in each softgel) Docusate Sodium 100 mg

Purpose: Stool Softener Laxative

Directions: adults and children 12 years and older: take 1-2 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor. Children under 12: consult a doctor. Do not exceed recommended dose.

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.

See product insert for prescribing information, precautions and warnings.

Store at 59°-77°F (15°-25°C)

This package is intended for in-patient institutional use only.
Keep this and all drugs out of the reach of children.

DIST. BY:
GERI-CARE PHARMACEUTICALS CORP.
1650 63rd Street,
Brooklyn, NY 11204
Product from USA or Canada

Repackaged By: Cardinal Health
Zanesville, OH 43701
LTB49503091114

Stool Softener
Docusate Sodium softgel
100 mg
LOT: XXXXXXXXXXXX EXP: XX/XX/XX

55154-1876-3
RPKD BY: Cardinal Health
Zanesville OH 43701

Stool Softener
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55154-1876-3
RPKD BY: Cardinal Health
Zanesville OH 43701

Package Label
Stool Softener
Docusate Sodium
100 mg each

QTY 30 Softgels

NDC 55154-1876-9 (CARDINAL HEALTH)
STOOL SOFTENER
DOCUSATE SODIUM 100 mg softgels
QTY 30

Active Ingredient (in each softgel) Docosate Sodium 100 mg
Purpose: Stool Softener Laxative

Directions: adults and children 12 years and older: take 1-2 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor. Children under 12: consult a doctor. Do not exceed recommended dose.

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.

See product insert for prescribing information, precautions and warnings.
Store at 55°-77°F (15°-25°C)

This package is intended for in-patient institutional use only.
Keep this and all drugs out of the reach of children.

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GERI-CARE PHARMACEUTICALS CORP.
1650 63rd Street,
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Product from USA or Canada

Repackaged By: Cardinal Health
Zanesville, OH 43701
LTB48469451113

Stool Softener
Docosate Sodium softgel
100 mg
LOT: XXXXXXXXXXXX EXP: XX/XX/XX
55154-1876-9
RPKD BY: Cardinal Health
Zanesville OH 43701

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Zanesville OH 43701

Card Label

Stool Softener

Docosate Sodium

100 mg each

**STOOL SOFTENER
DOCUSATE SODIUM
100 mg softgels**

LOT: xxxxxxxxxx EXP: xx/xx/xx

LTC48469450314



CUSTOMER ID

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55154-1876(NDC:57896-401)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (DOCUSATE)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40	
GELATIN	
GLYCERIN	
POLYETHYLENE GLYCOL 400	
PROPYLENE GLYCOL	
SORBITOL	
WATER	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
MANNITOL	

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:55154-1876-9	30 in 1 BLISTER PACK; Combination Product Type = C112160		
2	NDC:55154-1876-3	28 in 1 BLISTER PACK; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2000	

Labeler - Cardinal Health (188557102)**Registrant** - Geri-Care Pharmaceutical Corp (611196254)**Establishment**

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-1876)

Revised: 1/2015

Cardinal Health