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

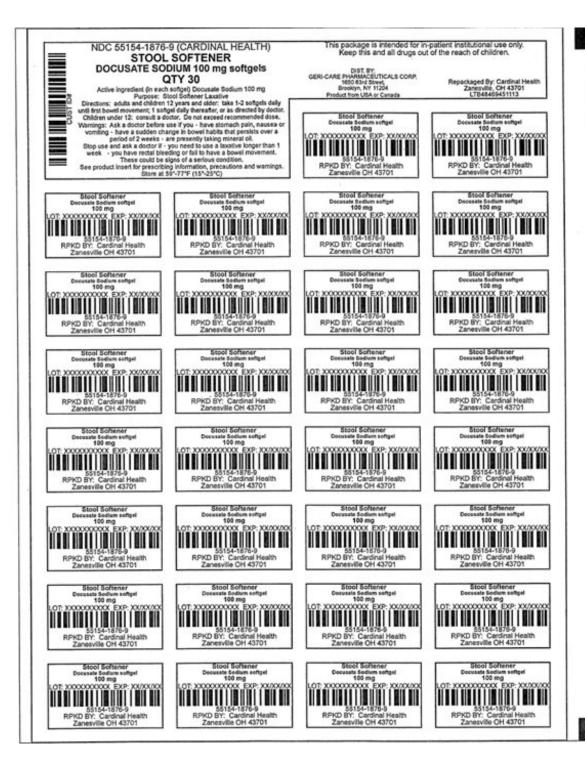
Package Label

Stool Softener

Docusate Sodium

100 mg each

QTY 30 Softgels



Card Label

Stool Softener

Docusate Sodium

100 mg each

STOOL SOFTENER DOCUSATE SODIUM 100 mg softgels

LOT: xxxxxxxx EXP: xx/xx/xx

LTC48469450314



STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information	
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HUMAN OTC DRUG Product Type

LABEL

Item Code (Source)

NDC:55154-

1876(NDC:57896-401)

Route of Administration

ORAL

DEA Schedule

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
DO CUSATE SO DIUM (DO CUSATE)	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			
Marketing Information				
Marketing Category	Application Number or Monog	raph Citation	Marketing Start D	Oate Marketing End Date
OTC monograph not final	part334		0 1/0 1/20 0 0	

Labeler - Cardinal Health (188557102)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

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

Revised: 4/2014 Cardinal Health