STOOL SOFTENER- docusate sodium capsule, liquid filled Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

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.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are

presently taking mineral oil.

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using a laxative. These could be sign of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health care 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

• take with a glass of water

adults and children 12 years of	take 1 to 3 softgels daily. This dose may be taken as a single daily
age and over	dose or in divided doses.
children 2 to under 12 years of age	take 1 softgel daily

Other information

- each softgel contains: sodium 6 mg
- store at 25°C (77°); excursions permitted between 15-30°C (59°-86°F)

Inactive ingredients

edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water sorbitan, sorbitol

Questions or comments?

Call **1-888-309-9030**

Principal Display Panel

Compare to the active ingredient of DulcoEase® Stool Softener

Gentle Relief

Stool Softener

Docusate sodium 100 mg

stool softener laxative

Fast, Dependable Relief of

Occasional Constipation

SOFTGELS

**This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of DulcoEase®.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Product Label

^{*}contains one or more of these ingredients



DOLLAR GENERAL Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-684
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)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics			
Color	ORANGE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51;SCU1;D2
Contains			

1	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55910-684- 25	1 in 1 BOX	10/31/2017		
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	10/31/2017	

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 12/2019 Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)