STOOL SOFTENER- docusate sodium capsule, liquid filled Family Dollar (FAMILY WELLNESS)

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

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

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN **DULCOEASE® STOOL SOFTENER†**

Stool Softener

Docusate Sodium 100 mg

Stool softener laxative

Gentle & 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: MIDWOOD BRANDS, LLC

10611 MONROE RD., MATTHEWS. NC 28105

Product Label



STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type		HUMAN OTC DRUG		Item Co	de (Source)	NDC:553	NDC:55319-044		
Route of Admi	nistratior	stration ORAL							
Active Ingree	dient/Act	tive Moiety							
Ingredient Name					Basis of Strength Streng				
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM						SODIUM	100 mg		
Inactive Ingr	edients								
Ingredient Name									
FD&C RED NO. 4	0 (UNII: WZ	(B9127XOA)							
FD&C YELLOW	IO. 6 (UNII:	H77VEI93A8)							
GELATIN (UNII: 2G86QN327L)									
GLYCERIN (UNII: PDC6A3C0OX)									
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)									
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)									
WATER (UNII: 059	QF0KO0R)								
SORBITOL (UNII:	506T60A25	R)							
SORBITAN (UNII:	6092ICV9R	U)							
Product Cha	ractoris	tice							
			C = = # =						
Color				no score 12mm					
Shape OVAI			Size						
Flavor			Imprint Code		P51;SCU1;D2				
Contains									
Packaging									
# Item Code		Package Description			Marketing Start M Date		eting End Date		
1 NDC:55319- 044-25	1 in 1 BO	n 1 BOX			06/30/2017 06/30/2		25		
1	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product								
Marketing	Inform	nation							
Marketing Category	Ар	Application Number or Mon Citation		jraph	Marketing Sta Date		Marketing End Date		
OTC monograph r final	ot part33	part334			06/30/2017 06/30/		25		

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)