STOOL SOFTENER- docusate sodium 100 mg capsule, liquid filled
We Care Distributor Inc.

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.

STOOL SOFTENER - Docusate Sodium Softgels, 100 mg

Drug Facts

Active ingredient (in each softgel) **Purpose**

Docusate sodium 100 mg.....Stool softener

Uses

■ for prevention of dry, hard stools

■ for relief of occasional constipation. This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

■ if you are presently taking mineral oil, unless directed by a doctor

■ when abdominal pain, nausea, or vomiting are present

■ for longer than 1 week, unless directed by a doctor

Ask a doctor before use if you have

noticed a sudden change in bowel habits that continues over a period of 2 weeks

Stop use and ask a doctor if

■ you have rectal bleeding

■ you fail to have a bowel movement after use

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

■ take with a glass of water

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

■ children 2 to under 12 years of age: take 1 softgels daily

■ children under 2 years of age: consult a physician.

Other information

■ each softgel contains sodium 6 mg

■ store at controlled room temperature 15°-30°C (59°-86°F)

■ read all product information before using

Inactive ingredients

FD&C Red # 40, FD&C Yellow #6, gelatin, glycerine, polyethylene glycol 400, propylene glycol, purified water, sorbitol solution, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

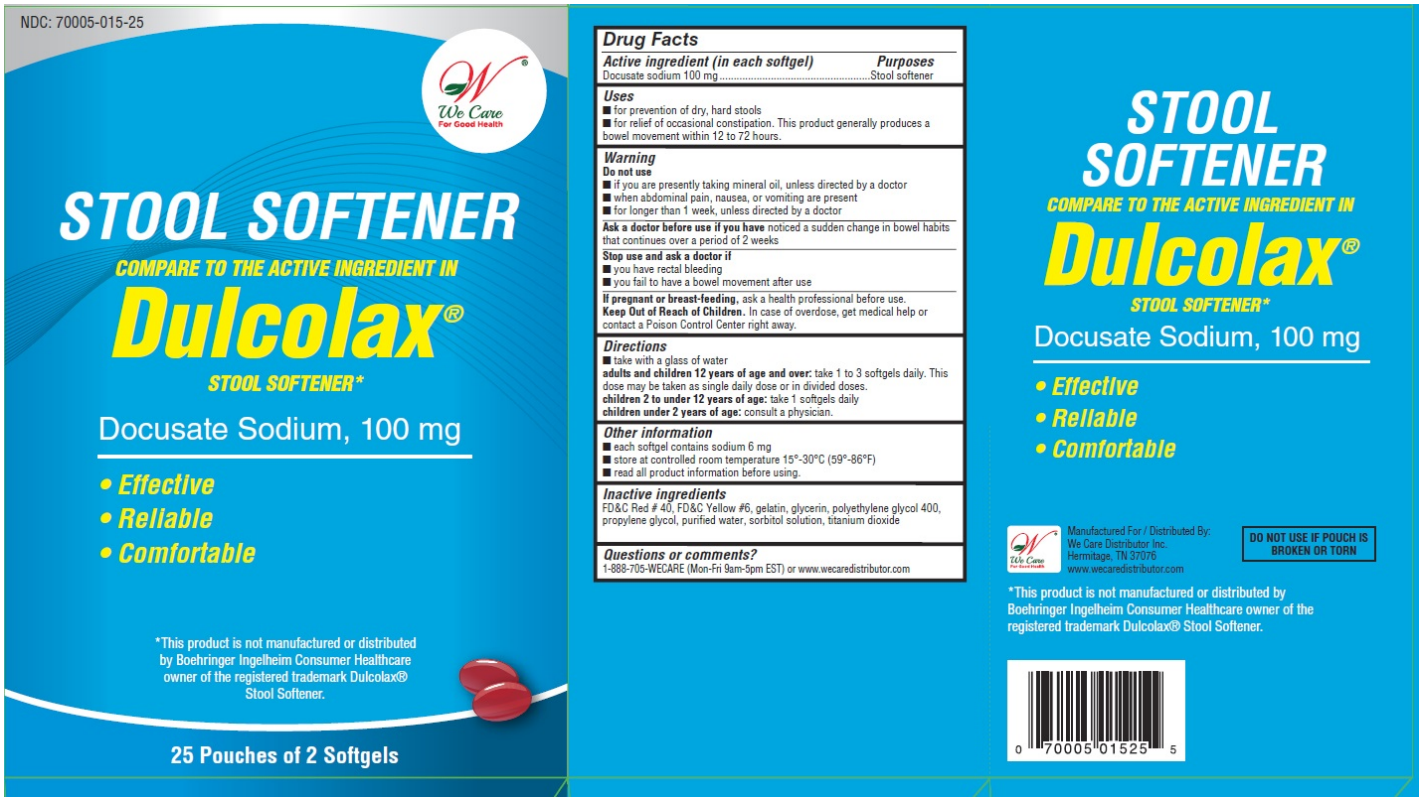
Compare to the Active Ingredients in Dulcolax® Stool Softener

STOOL SOFTENER

Docusate Sodium Softgels, 100 mg

TO OPEN
PUSH IN TAB AND PULL OUT

25 Pouches of 2 Softgels Each



STOOL SOFTENER

docusate sodium 100 mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70005-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	200 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 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	125
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-015-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-015-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-015-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	03/07/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(70005-015)