# NON-HABIT FORMING STOOL SOFTENER- docusate sodium capsule, liquid filled Rugby Laboratories 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.

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## **Drug Facts**

## Active ingredient (in each softgel)

Docusate Sodium 100 mg

## Purpose

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 currently 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

if you notice a sudden change in bowel habits that persists 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

These could be signs of a serious condition.

### 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**

adults and children over 12 years of age	take 1 to 3 softgels preferably at bedtime
children 6-12 years of age	take 1 softgel at bedtime
children under 6 years	ask a doctor

#### Other information

- each softgel contains: sodium 6 mg
- store between 15°-30°C (59°-86°F)

## **Inactive ingredients**

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special.

### Questions or comments?

1-800-645-2158

## **Principal Display Panel**

COMPARE TO ACTIVE INGREDIENT IN COLACE®\*

NON-HABIT FORMING

Stool Softener Laxative

Docusate Sodium USP, 100 mg

SOFTGEL CAPSULES

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

\*Rugby Laboratories is not affiliated with the owner of the trademark Colace®.

Distributed by: Rugby Laboratories

31778 Enterprise Drive

Livonia, MI 48150

www.rugbylaboratories.com

#### **Product Label**



Rugby Stool Softener Laxative Softgel

## NON-HABIT FORMING STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information	roduct Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0536-3756	
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			
FD&C YELLOW NO. 6			
GELATIN			
GLYCERIN			
POLYETHYLENE GLYCOLS			
PROPYLENE GLYCOL			
WATER			
SORBITOL			

Product Characteristics			
Color	ORANGE (orange)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	P51
Contains			

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:0536-3756-01	100 in 1 BOTTLE			
	NDC:0536-3756-10	1000 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/29/2012	

## Labeler - Rugby Laboratories Inc (191427277)

## $\pmb{Registrant - } \ {\tt P} \ {\tt and} \ {\tt L} \ {\tt Development} \ {\tt of} \ {\tt New York} \ {\tt Corporation} \ (800014821)$

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