

**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.

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® NDC 0536-3756-10

COMPARE TO ACTIVE INGREDIENT IN COLACE®*

NON-HABIT FORMING

Stool Softener

LAXATIVE
Docusate Sodium USP, 100 mg

1000 SOFTGEL CAPSULES

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

Drug Facts
Purpose Stool softener
Active ingredient (in each softgel) Docusate Sodium 100 mg
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 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 ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water and sorbitol special.
Questions or comments? 1-800-645-2158 This is a bulk package. Dispense contents with a child-resistant closure in a light, light-resistant container as defined in the USP. *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
R-58 Rev. 03/13
625
R0313B Re-order No. 370215
L09RUG1000

Lot No:
Exp. Date:

05363756107

Rugby Stool Softener Laxative Softgel

NON-HABIT FORMING STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-3756
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

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
1	NDC:0536-3756-01	100 in 1 BOTTLE		
2	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)

Revised: 4/2013

Rugby Laboratories Inc