

NON-HABIT FORMING STOOL SOFTENER- docusate sodium capsule, liquid filled
Aidarex Pharmaceuticals LLC

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.

Non-Habit Forming Stool Softener Laxative

Active Ingredient (in each softgel capsule)

Docusate Sodium 100mg

Purpose

Stool softener

Uses

- Relieves occasional constipation.
- Generally produces bowel movement within 12 to 72 hours.

Warnings - Do not use

- for longer than one week
- if you are taking mineral oil
- when abdominal pain, nausea, or vomiting are present

Ask a doctor before use if

you have a sudden change in bowel habits that lasts over two weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

- you experience rectal bleeding
- you fail to have a bowel movement after using this product

These may indicate a serious condition.

If pregnant or breastfeeding

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

- **adults and children over 12 years and over:** 1 capsule once daily or in divided doses
- **children 6 to under 12 years:** 1 capsule once daily
- **children under 6 years:** ask a doctor

Other information

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

Each capsule contains sodium 6mg

Inactive Ingredients

edible white ink, FDandC Red No. 40, FDandC Yellow No. 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special.

Questions or comments?

Call 1-800-645-2158, 9am - 5am ET Monday - Friday

Product Labeling

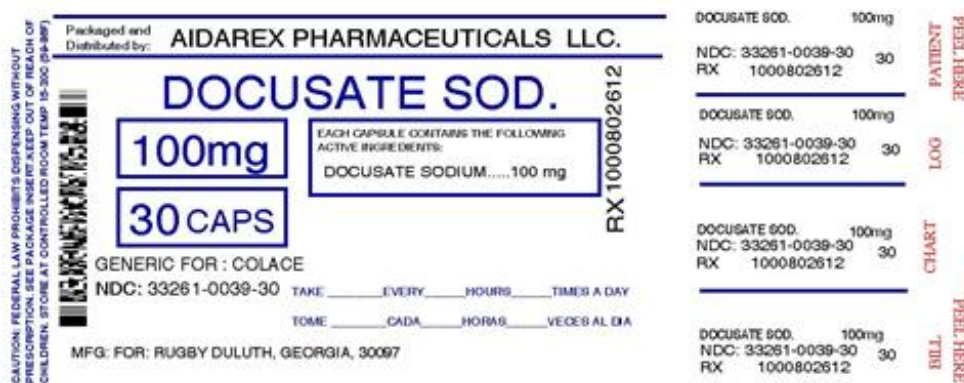
Rugby Extra Strength Stool Softener Laxative
 Docusate Sodium USP, 250mg

*Rugby Laboratories, Inc is not affiliated with the owner of the trademark Colace(r).

Rugby stool softener Laxative is distributed by Rugby Laboratories, Inc.

Mfd for: Rugby Laboratories, Inc
 Duluth Georgia 30097
 www.rugbylaboratories.com

Repackaged By:
 Aidarex Pharmaceuticals, LLC.
 Corona, CA 92880



NON-HABIT FORMING STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-039(NDC:0536-3756)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg
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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:33261-039-00	100 in 1 BOTTLE		
2	NDC:33261-039-02	120 in 1 BOTTLE		
3	NDC:33261-039-10	10 in 1 BOTTLE		
4	NDC:33261-039-20	20 in 1 BOTTLE		
5	NDC:33261-039-30	30 in 1 BOTTLE		
6	NDC:33261-039-60	60 in 1 BOTTLE		
7	NDC:33261-039-90	90 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 - Aidarex Pharmaceuticals LLC (801503249)