

**EXTRA STRENGTH STOOL SOFTENER LAXATIVE - docusate sodium capsule, liquid filled**  
**State of Florida DOH Central Pharmacy**

*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 250 mg

**Purpose**

Stool softener

**Uses**

- for the 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 more 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 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 12 years of age and over:** take 1 softgel daily or as directed by a doctor
- **children under 12 years of age:** take as directed by a doctor

**Other information**

- **each softgel contains:** sodium 15 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**

Distributed by: Rugby Laboratories  
31778 Enterprise Drive  
Livonia, MI 48150  
www.rugbylaboratories.com

This Product was Repackaged By:

### State of Florida DOH Central Pharmacy

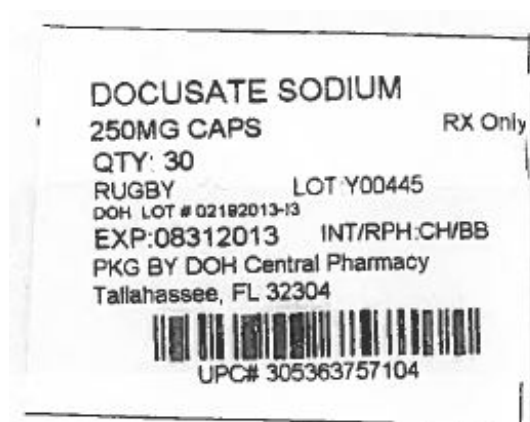
104-2 Hamilton Park Drive  
Tallahassee, FL 32304  
USA

And supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-0902-1	250 MG	30 Capsules in a Blister Pack	orange	0536-3757

### PACKAGE LABEL

Label Image for **53808-0902**  
**250mg**



## EXTRA STRENGTH STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53808-0902(NDC:0536-3757)	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	250 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
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: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
<b>Product Characteristics</b>				
<b>Color</b>	ORANGE (orange)	<b>Score</b>	no score	
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	20mm	
<b>Flavor</b>		<b>Imprint Code</b>	P20	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53808-0902-1	30 in 1 BLISTER PACK		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part334	01/01/2014		

**Labeler** - State of Florida DOH Central Pharmacy (829348114)

### Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0902)