

**EXTRA STRENGTH STOOL SOFTENER LAXATIVE - docusate sodium capsule, liquid filled  
Dispensing Solutions, 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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**Docusate Sodium ES**

**Active Ingredient (in each softgel)**

Docusate Sodium 250mg

**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
- **children under 12 years:** ask a doctor

**Other information**

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

Each capsule contains sodium 15mg

### Inactive Ingredients

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

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

### Package Label

NDC 66336-0010-XX

<p>BULK SOURCE DATA</p> <p>MFD. FOR: RUGBY LABORATORIES, INC. DULUTH, GA 30097</p> <p>PRODUCT ID: RED OBLONG SOFT GELATIN CAPSULE PRINTED P20</p> <p>BULK SOURCE NDC: 00536-3757-10 MFR. LOT: XXXXXX PEDIGREE #: 18520314 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 <p><b>DOCUSATE SODIUM ES 250 mg</b></p> <p><b>XX SOFTGELS</b></p> <p><b>NDC 66336-0010-XX</b></p> <p><b>PRODUCT # 416-XX</b></p> <p>ACTIVE INGREDIENT (IN EACH SOFTGEL CAPSULE) DOCUSATE SODIUM USP . . . . 250 mg (PURPOSE: STOOL SOFTENER) FD&amp;C YELLOW No. 6</p> <p>Rev. Date: 08/10</p> <p>LOT# SAMPLE EXP: 00-00 Rx # 22034924</p>	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE BETWEEN 59°- 86° F. SEE USP.</p> <p>416-XX NDC 66336-0010-XX DOCUSATE SODIUM ES 250 mg XX SOFTGELS LOT # SAMPLE EXP: 00-00 MN 00536-3757-10 RX# 22034924</p> <p>416-XX NDC 66336-0010-XX DOCUSATE SODIUM ES 250 mg XX SOFTGELS LOT # SAMPLE EXP: 00-00 MN 00536-3757-10 RX# 22034924</p> <p>416-XX NDC 66336-0010-XX DOCUSATE SODIUM ES 250 mg XX SOFTGELS LOT # SAMPLE EXP: 00-00 MN 00536-3757-10 RX# 22034924</p>  <p>Packaged Exclusively By: <b>DISPENSING SOLUTIONS<sup>INC</sup></b> Santa Ana, CA 92704</p>
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## EXTRA STRENGTH STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66336-010(NDC:0536-3757)
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	250 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	20mm
Flavor		Imprint Code	P20
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66336-010-20	20 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** - Dispensing Solutions, Inc. (066070785)

**Registrant** - PSS World Medical, Inc. (101822682)

### Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(66336-010) , repack(66336-010)