# 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

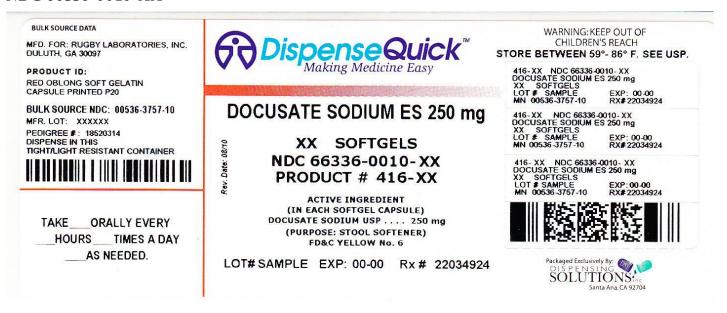
## **Product Labeling**

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



## EXTRA STRENGTH STOOL SOFTENER LAXATIVE

**Ingredient Name** 

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	nem coue (course)	,
Route of Manimistration	Oldin		
Active Ingredient/Active Moiety			

**Basis of Strength** 

Strength

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: 6 DC9 Q16 7 V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	orange (orange)	Score	no score
Shape	OVAL (OVAL)	Size	20 mm
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)

Revised: 9/2012 Dispensing Solutions, Inc.