# NON-HABIT FORMING STOOL SOFTENER- docusate sodium capsule, liquid filled Rebel Distributors Corp

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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# **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

## **Principal Display Panel**



# NON-HABIT FORMING STOOL SOFTENER docusate sodium capsule, liquid filled Product Information Product Type HUMAN OTC DRUG LABEL Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DOCUSATE SODIUM (DOCUSATE)	DOCUSATE SODIUM	100 mg		

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40	
FD&C YELLOW NO. 6	
GELATIN	
GLYCERIN	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
WATER	
SORBITOL	

Product Characteristics				
Color	orange (orange)	Score	no score	
Shape	OVAL (OVAL)	Size	13mm	
Flavor		Imprint Code	P51	
Contains				

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:42254-125-30	30 in 1 BOTTLE				
2	NDC:42254-125-60	60 in 1 BOTTLE				
3	NDC:42254-125-00	100 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** - Rebel Distributors Corp (118802834)

# Registrant - PSS World Medical, Inc. (101822862)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
PSS World Medical, Inc.		79 1528 623	REPACK(42254-125)

Establishment			
Name	Address	ID/FEI	Business Operations

STAT RX USA LLC	786036330	REPACK(42254-125)

Establishment			
Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-125), REPACK(42254-125)

Establishment			
Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-125), REPACK(42254-125)

Establishment			
Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-125)

Establishment			
Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-125), REPACK(42254-125)

Revised: 1/2012 Rebel Distributors Corp