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.

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	Item Code (Source)	NDC:42254-125(NDC:0536-3756)
Route of Administration	ORAL		

Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength Strength					
DO CUSATE SO DIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg			

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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

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

P	Packaging								
#	Item Code	Package Description	Marketing Start Date	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	Business Operations
PSS World Medical, Inc.		791528623	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)

Establishmen	t		
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