PROMOLAXIN- docusate sodium tablet
STAT Rx USA LLC

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.

Promolaxin™ Docusate Sodium Stool Softener

Active ingredient

Docusate Sodium 100 mg

Purpose

Stool Softener

Uses

- for relief of occasional constipation (irregularity). This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

- laxative products for longer than one week unless directed to do so by a doctor
- if you are presently taking mineral oil unless told to do so by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 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 doctor 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 older:

Take 1 tablet as needed, not to exceed more than 3 tablets daily, or as directed by a doctor.

Children under 12 years of age:

Consult a doctor before use.

Other information

- Each tablet contains: **Calcium 40 mg**
- Each tablet contains: **Sodium 10 mg**
- Store at room temperature.
- Do not use if imprinted safety seal is broken or missing.

Inactive ingredients

Croscarmellose Sodium, Dicalcium Phosphate, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Silica, Sodium Benzoate, Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event,

please contact 714-875-6316.

Manufactured for: Physician's Science and Nature, Inc.

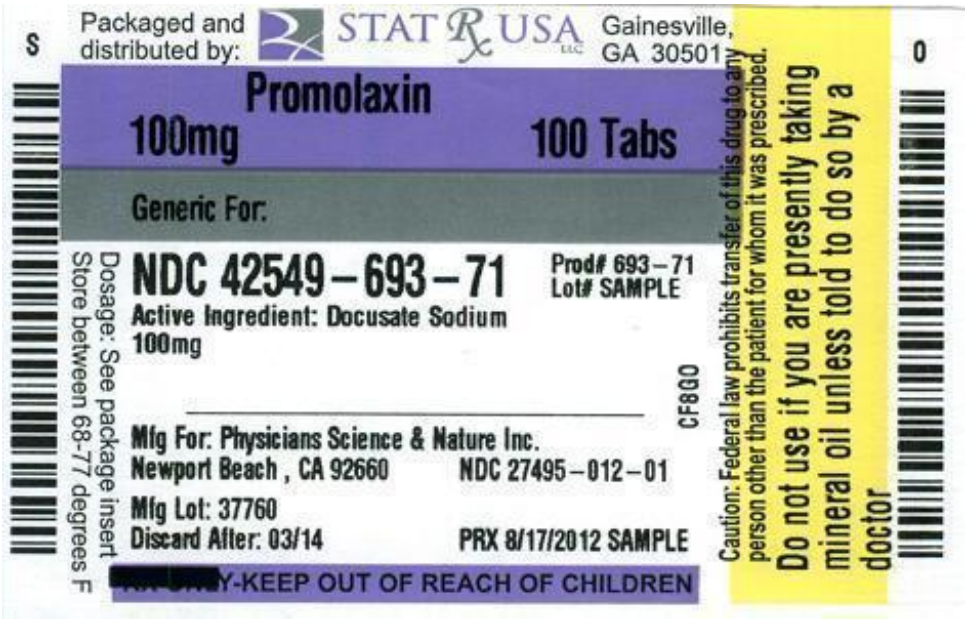
220 Newport Center Drive 11-634, Newport Beach, CA 92660

Relabeling and Repackaging by:

STAT Rx USA LLC

Gainesville, GA 30501

PACKAGE LABEL - PROMOLAXIN 100 MG TABLETS



PROMOLAXIN
docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42549-693(NDC:27495-012)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	GPI;S1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42549-693-71	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/15/2011	

Labeler - STAT Rx USA LLC (786036330)

Registrant - PSS World Medical Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
STAT Rx USA LLC		786036330	relabel(42549-693) , repack(42549-693)

Revised: 9/2012 STAT Rx USA LLC