

**PROMOLAXIN- docusate sodium tablet**  
**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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**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

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68258-4987-00

**BULK SOURCE DATA**  
MFD. FOR: PHYSICIAN'S SCIENCE AND NATURE, INC.  
NEWPORT BEACH, CA 92660  
**PRODUCT ID:**  
WHITE ROUND BOTTLE WHITE / BLACK / TEAL LABEL WITH PICTURE OF A FLOWER PRINTED NDC 27495-012-01  
**BULK SOURCE NDC: 27495-0012-01**  
MFR. LOT: SAMPLE  
PEDIGREE #: 4860  
DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER

**DispenseQuick™**  
Making Medicine Easy

**PROMOLAXIN 100 mg**  
**100 TABLETS**  
**NDC 68258-4987-00**  
**PRODUCT # 4P041K**

Rev. Date: 04/13

**ACTIVE INGREDIENT (IN EACH TABLET):**  
DOCUSATE SODIUM 100 mg  
(PURPOSE: STOOL SOFTENER)

**LOT#SAMPLE EXP: 00-00 Rx # 32220621**

**WARNING: KEEP OUT OF CHILDREN'S REACH**  
**STORE AT ROOM TEMPERATURE. SEE USP.**

4P041K NDC 68258-4987-00  
PROMOLAXIN 100 mg  
100 TABLETS  
LOT # SAMPLE EXP: 00-00  
MN 27495-0012-01 RX# 32220621

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PROMOLAXIN 100 mg  
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4P041K NDC 68258-4987-00  
PROMOLAXIN 100 mg  
100 TABLETS  
LOT # SAMPLE EXP: 00-00  
MN 27495-0012-01 RX# 32220621

TAKE \_\_\_ TABLET(S)  
ORALLY \_\_\_ TIMES A DAY.  
DO NOT USE FOR LONGER  
THAN ONE WEEK UNLESS  
DIRECTED BY A DOCTOR.

Packaged Exclusively By:  
**DISPENSING SOLUTIONS, Inc.**  
Santa Ana, CA 92704

## PROMOLAXIN

docusate sodium tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68258-4987(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:68258-4987-0	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** - Dispensing Solutions, Inc. (066070785)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-4987) , repack(68258-4987)

