# PROMOLAXIN- docusate sodium tablet Unit Dose Services

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™ Docus ate 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 andchildren 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?

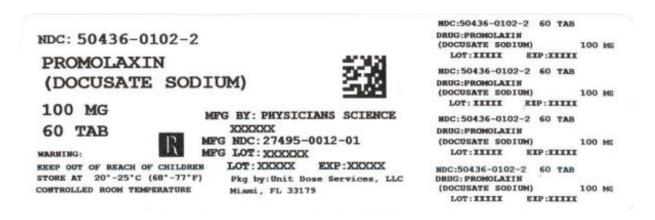
If you have any questions or comments, or to report an adverse event, please contact 714-875-6316.

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

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

### PROMOLAXIN (DOCUSATE SODIUM) TABLET

**Ingredient Name** 



# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:50436-0102(NDC:27495-012) Route of Administration ORAL DEA Schedule Active Ingredient/Active Moiety

**Basis of Strength** 

Strength

DOCUSATE SODIUM (DOCUSATE)

DOCUSATE SODIUM

100 mg

Inactive	Ingredients

mactive ingredients	
Ingredient Name	Strength
HYPROMELLOSES	
CROSCARMELLOSE SODIUM	
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US	
MAGNESIUM STEARATE	
CELLULOSE, MICRO CRYSTALLINE	
POLYETHYLENE GLYCOLS	
STARCH, CORN	
SILICON DIO XIDE	
SO DIUM BENZO ATE	
STEARIC ACID	

	oduct Characteristic	Duaduat
CS	oduct Characteristic	Proauct
ı	Juuci Characteristi	Pivuuci

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50436-0102-1	30 in 1 BOTTLE			
2	NDC:50436-0102-2	60 in 1 BOTTLE			
3	NDC:50436-0102-3	100 in 1 BOTTLE			

## Marketing Information

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

# Labeler - Unit Dose Services (831995316)

# Registrant - Unit Dose Services (831995316)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unit Dose Services		831995316	REPACK(50436-0102)	

Revised: 4/2011 Unit Dose Services