# STOOL SOFTENER WITH LAXATIVE- docusate sodium and sennosides tablet, film coated Geri-Care Pharmaceutical 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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Gericare 303B (304)

# **Active ingredient (in each tablet)**

Docusate Sodium 50 mg Sennosides 8.6 mg

### **Purpose**

Stool softener

Stimulant laxative

#### Uses

- relieves occasional constipation (irregularity)
- this product generally produces bowel movement in 6 to 12 hours

# **Warnings**

#### Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are presently taking mineral oil, unless directed 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 or fail to have a bowel movement after use of a laxative. These could

be signs of a serious condition.

**If pregnant or breast-feeding,** 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**

• Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses

adults and children 12 years and	take 2-4 tablets
over	daily

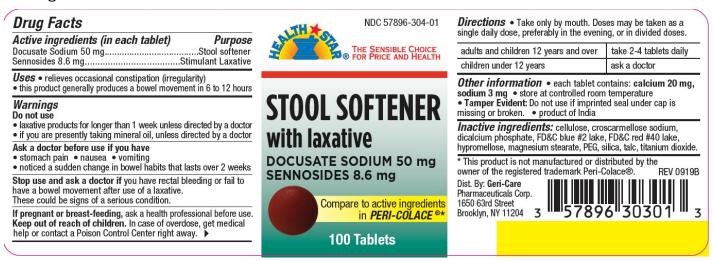
#### Other information

- each tablet contains: calcium 20 mg, sodium 3 mg
- store at controlled room temperature
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.
- product of India

# **Inactive ingredients**

cellulose, croscarmellose sodium, dicalcium phosphate, FD&C blue #2 lake, FD&C red #40 lake, hypromellose, magnesium stearate, PEG, silica, talc, titanium dioxide.

### **Package Label**



#### STOOL SOFTENER WITH LAXATIVE

docusate sodium and sennosides tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-304	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg		
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg		

Inactive Ingredients			
Ingredient Name	Strength		
TALC (UNII: 7SEV7J4R1U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28 O L 1 HH48)	
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	PSD21	
Contains				

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:57896-304-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 19		
2 NDC:57896-304-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 19		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/0 1/20 19	

# Labeler - Geri-Care Pharmaceutical Corp (611196254)

# $\pmb{Registrant - \text{Geri-Care Pharmaceutical Corp (611196254)}}$

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Geri-Care Pharmaceuticals, Corp		611196254	repack(57896-304)	

Revised: 12/2019 Geri-Care Pharmaceutical Corp