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.

Gericare 303

Active ingredient (in each tablet)

Docusate Sodium 50 mg Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- relieves occasional constipation (irregularity)
- 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
- each tablet contains: sodium 6 mg VERY LOW SODIUM
- store at 15°-30°C (59°-86°F), protect from excessive moisture

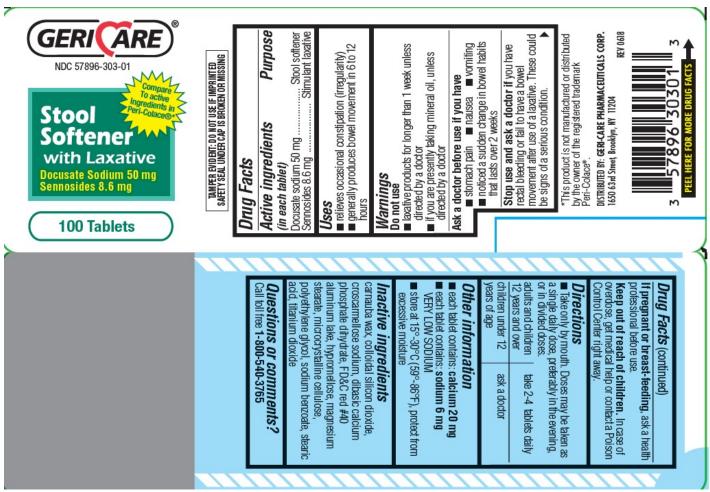
Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?

Call toll free 1-800-540-3765

Package Label



STOOL SOFTENER WITH LAXATIVE

docusate sodium and sennosides tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-303
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		
DO CUSATE SODIUM (UNII: F05Q2T2JA0) (DO CUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg		

Inactive Ingredients				
Ingredient Name	Strength			
CARNAUBA WAX (UNII: R12CBM0EIZ)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
HYPROMELLOSES (UNII: 3NXW29 V3WO)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
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	TCL097
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:57896-303-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	
	2 NDC:57896-303-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/0 1/20 14	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Establishment			
Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceuticals, Corp		611196254	repack(57896-303)

Revised: 11/2018

Geri-Care Pharmaceutical Corp