STOOL SOFTENER WITH LAXATIVE- docusate sodium and sennosides tablet, film coated
PHARMACY VALUE ALLIANCE, 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.

PV303B (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 over	take 2-4 tablets daily

children under 12 years of age	ask a doctor

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:68016-623
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	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: 3NXW29V3WO)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-623-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2019	
2	NDC:68016-623-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/01/2019	

Labeler - PHARMACY VALUE ALLIANCE, LLC (101668460)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceuticals, Corp		611196254	repack(68016-623)

Revised: 12/2019 PHARMACY VALUE ALLIANCE, LLC