

2 IN 1 LAXATIVE STOOL SOFTENER AND STIMULANT LAXATIVE- stool softener-stimulant laxative tablet, coated
RITE AID

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.

209R Rite aid 11822 8005 Stool Softener / Stimulant Laxative 100 count

DRUG FACTS

Active ingredients (each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purposes

Stool softener

Stimulant laxative

Uses

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

Do not use

- laxative products for longer than 1 week unless told 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 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 older

take 2-4 tablets daily

children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take upto 1 tablet daily
children under 2 years	ask a doctor

Other information

- **each tablet contains:** calcium 20 mg, sodium 6 mg (VERY LOW SODIUM)
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

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 1-877-290-4008



2 IN 1 LAXATIVE STOOL SOFTENER AND STIULANT LAXATIVE

stool softener-stimulant laxative tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-8005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL097
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-8005-5	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/01/2020	

Labeler - RITE AID (014578892)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(11822-8005)