

**STOOL SOFTENER-STIMULANT LAXATIVE- stool softener-stimulant laxative tablet, coated
Kroger Company**

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 Kroger Company Stool Softener / Stimulant Laxative

active ingredients (each tablet)

Docusate Sodium 50 mg

Sennosides 8.6 mg

CARNAUBA WAX, COLLOIDAL SILICON DIOXIDE, CROSCARMELLOSE SODIUM, DIBASIC CALCIUM PHOSPHATE DIHYDRATE, FD-C RED NO. 40 ALUMINUM LAKE, HYPROMELLOSE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL, SODIUM BENZOATE, STEARIC ACID, TITANIUM DIOXIDE.

Stool Softener

Stimulant Laxative

RELIEVES OCCASIONAL CONSTIPATION

GENERALLY PRODUCES BOWEL MOVEMENT IN 6-12 HOURS

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 \
CHILDREN 6 TO UNDER 12 YEARS: 1-2 TABLETS \DAILY \
CHILDREN 2 TO UNDER 6 YEARS;]
1 TABLET DAILY
CHILDREN UNDER 2 YEARS: ASK A DOCTOR

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

KEEP OUT OF REACH OF CHILDREN. IN CASE OF OVERDOSE, GET MEDICAL HELP OR
CONTACT A POISON CONTROL CENTER RIGHT AWAY

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STOOL SOFTENER-STIMULANT LAXATIVE

stool softener-stimulant laxative tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-209	
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)				
CROSCARMELLOSE 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:41226-209-06	60 in 1 BOTTLE; 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 - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(41226-209)

Revised: 6/2020

Kroger Company