

**SENNOSIDES AND DOCUSATE SODIUM- sennosides and docusate sodium tablet, film coated**  
**TIME CAP LABORATORIES, INC**

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**209R TCL Laxative Docusate Sodium 50 mg Sennosides 8.6 mg Tablets**

**DRUG FACTS**

***Active ingredients (in 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

***Warnings***

**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 (1-800-222-1222).

***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 up to 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 aluminium lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide

***Questions or comments?***

**call 1-877-290-4008**

Code # 209R

PLD 209R

P.O.# ??????????

PRODUCT # BK000011

**Time-Cap Labs Inc**

7 Michael Avenue Farmingdale NY 11735

**BULK SHIPMENT INTENDED FOR MANUFACTURING,  
PROCESSING OR REPACKAGING**

TCL Control # ???????

THEORETICAL QUANTITY: ???????????  
CTN# ??? OF ??? CTNS.

NDC 49483-097-00

Product SENNOSIDES AND DOCUSATE SODIUM TABLETS,  
8.6 MG AND 50 MG (FILM COATED, RED)

DEBOSSSED: TCL 097  
MADE IN THE USA

Each Tablet Contains: CALCIUM SENNOSIDES 8.6 MG  
DOCUSATE SODIUM 50 MG

**STORE AT 25°C (77°F) - Excursions permitted between  
15°-30°C (59°-86°F) IN ORIGINAL BULK CONTAINERS**

**REPACKAGE IMMEDIATELY UPON RECEIPT**

**IMPORTANT**

This is a bulk shipment intended to be repackaged and labeled immediately upon receipt in strict conformance with the applicable requirements of the Food, Drug and Cosmetic Act, and regulations thereunder or the laws and regulations of the country of destination.

Upon request Time-Cap Labs will supply stability supported packaging specifications. Our responsibility ceases upon removal of the product from the bulk containers or failure to request or follow Time-Cap Labs packaging and/or labeling specifications.

Ship To: PL DEVELOPMENTS  
275 GRAND BLVD  
WESTBURY, NY. 11590

REV 07 18

NDC 49483-097-01

**timely** <sup>1</sup>Compare to the active ingredients in Colace® 2-IN-1

# 2-IN-1 LAXATIVE

Docosate Sodium 50 mg,  
Sennosides 8.6 mg

**Stool Softener + Stimulant Laxative**

- Gentle, Dependable
- Relief in 6-12 Hours

**100 TABLETS** 

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

**Drug Facts**

**Active ingredients (in each tablet) Purposes**  
 Docosate sodium 50 mg ..... Stool softener  
 Sennosides 8.6 mg ..... Stimulant laxative

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- relieves occasional constipation (irregularity)
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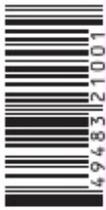
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**Drug Facts (continued on back of label)**

This product is not manufactured or distributed by Abbott's Consumer Healthcare Inc., owner of the registered trademark Colace® 2-IN-1.

Manufactured by:  
 Time-Cap Labs, Inc.  
 7 Michael Avenue,  
 Farmingdale, NY 11735  
 209R 0724

  
 4 9 4 8 3 1 2 1 0 0 1  
 3

**Varnish Omit Area**

**LOT:**  
**EXP.:**  
**PEEL HERE**

Adhesive Area

**Drug Facts (continued)**

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## SENNOSIDES AND DOCUSATE SODIUM

sennosides and docosate sodium tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-097
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength

<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40 ALUMINUM LAKE</b> (UNII: 6T47AS764T)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL097
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-097-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2010	
2	NDC:49483-097-00	100000 in 1 CARTON; Type 0: Not a Combination Product	01/01/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/01/2010	

**Labeler** - TIME CAP LABORATORIES, INC (037052099)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-097)