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

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.

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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.

#### **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

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)

DEBOSSED: 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

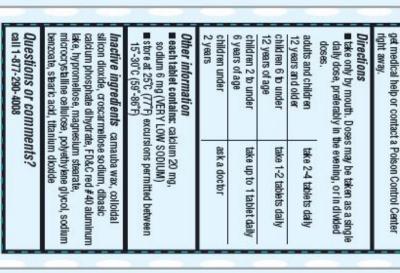
### IMPORTANT

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 Adhesive Area



Drug Facts (continued)

Keep out of reach of children. In case of overdose,



## SENNOSIDES AND DOCUSATE SODIUM

sennosides and docusate sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-097
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

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

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	<b>1</b> 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 not final	part334	01/01/2010	

# Labeler - TIME CAP LABORATORIES, INC (037052099)

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

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

Revised: 11/2021 TIME CAP LABORATORIES, INC