

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.

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

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

Drug Facts (continued)

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 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?
call 1-877-290-4008

Adhesive Area

NDC 49483-097-01

timely †Compare to the active ingredients in Colace® 2-In-1

2-IN-1 LAXATIVE
Docusate Sodium 50 mg, Sennosides 8.6 mg

Stool Softener + Stimulant Laxative

- Gentle, Dependable
- Relief in 6-12 Hours

100 TABLETS Actual Size

Drug Facts

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

Drug Facts continued on back of label

This product is not manufactured or distributed by Avrio Health L.P., 200R, 1120
Manufactured by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735

LOT #: 3
EXP. DATE: 9

10760 10760 483 483 64
3

Varnish Omit Area

PEEL HERE

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

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	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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
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			

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 not final	part334	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)

